

# Georgia Rules and Regulations Administrative Bulletin for February 2020

## OFFICE OF SECRETARY OF STATE ADMINISTRATIVE PROCEDURE DIVISION

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Final rules filed with the Georgia Secretary of State during the month of *February 2020*:

### Table of Contents

| Department   | Rules List   | Action    | Filed   | Effective     | Page |
|--|--|-----------|---------|---------------|------|
| 40. RULES OF GEORGIA<br>DEPARTMENT OF<br>AGRICULTURE | <a href="#">40-32-1-.01</a> --- <a href="#">40-32-1-.06</a>  | adopted   | Feb. 10 | Mar. 1, 2020  | 4    |
|  | <a href="#">40-32-2-.01</a> --- <a href="#">40-32-2-.12</a>  | adopted   | Feb. 10 | Mar. 1, 2020  | 9    |
|  | <a href="#">40-32-3-.01</a> --- <a href="#">40-32-3-.11</a>  | adopted   | Feb. 10 | Mar. 1, 2020  | 24   |
| 111. RULES OF DEPARTMENT<br>OF COMMUNITY HEALTH      | <a href="#">111-8-37-.07</a> , <a href="#">111-8-37-.08</a> ,<br><a href="#">111-8-37-.11</a> , <a href="#">111-8-37-.13</a> ,<br><a href="#">111-8-37-.21</a> | amended   | Feb. 28 | Mar. 19, 2020 | 35   |
|  | <a href="#">111-8-62-.03</a> , <a href="#">111-8-62-.09</a> ,<br><a href="#">111-8-62-.11</a>  | amended   | Feb. 28 | Mar. 19, 2020 | 41   |
|  | <a href="#">111-8-63-.03</a> , <a href="#">111-8-63-.09</a> ,<br><a href="#">111-8-63-.10</a> , <a href="#">111-8-63-.20</a>                                   | amended   | Feb. 28 | Mar. 19, 2020 | 48   |
| 160. RULES OF GEORGIA<br>DEPARTMENT OF EDUCATION     | <a href="#">160-1-4-.270</a>   | submitted | Feb. 12 | Mar. 11, 2020 | 61   |
|  | <a href="#">160-4-2-.48</a>  | amended   | Feb. 20 |               | 62   |
| 195. GEORGIA BOARD FOR<br>HEALTH CARE WORKFORCE      | <a href="#">195-1-.01</a>  | adopted   | Feb. 3  | Feb. 23, 2020 | 68   |
| 266. GEORGIA EMERGENCY<br>MANAGEMENT AGENCY          | <a href="#">266-1-.01</a> --- <a href="#">266-1-.19</a>  | repealed  | Feb. 6  | Feb. 26, 2020 | 70   |

| <b>Department</b>                                     | <b>Rules List</b>  | <b>Action</b>          | <b>Filed</b> | <b>Effective</b>  | <b>Page</b> |
|---|--|------------------------|--------------|-------------------|-------------|
| 290. RULES OF DEPARTMENT OF HUMAN SERVICES            | <a href="#">290-7-1-.17</a>  | non-substantive change | Feb. 24      | February 24, 2020 | 74          |
| 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES | <a href="#">391-2-4-.04</a>  | amended                | Feb. 10      | Mar. 1, 2020      | 76          |
|   | <a href="#">391-2-4-.18</a>  | adopted                | Feb. 17      | Mar. 1, 2020      | 79          |
|   | <a href="#">391-3-17-.02, 391-3-17-.05, 391-3-17-.07, 391-3-17-.10</a> | amended                | Feb. 26      | Mar. 17, 2020     | 83          |
|   | <a href="#">391-4-2-.72</a>  | adopted                | Feb. 10      | Mar. 1, 2020      | 229         |
| 480. RULES OF GEORGIA STATE BOARD OF PHARMACY         | <a href="#">480-13-.05</a>   | amended                | Feb. 4       | Feb. 24, 2020     | 230         |

Final rules filed with the Georgia Secretary of State that became effective *February 2020*:

| Department   | Rules List   | Action   | Filed         | Effective |
|--|--|----------|---------------|-----------|
| 40. RULES OF GEORGIA<br>DEPARTMENT OF<br>AGRICULTURE | <a href="#">40-10-1-.20</a>  | amended  | Jan. 31, 2020 | Feb. 20   |
|  | <a href="#">40-12-4-.01</a>  | amended  | Jan. 15, 2020 | Feb. 4    |
| 160. RULES OF GEORGIA<br>DEPARTMENT OF EDUCATION     | <a href="#">160-5-1-.10</a> , <a href="#">160-5-1-.28</a>  | amended  | Jan. 16, 2020 | Feb. 5    |
| 183. STATE ELECTION BOARD                            | <a href="#">183-1-12-.01</a> --- <a href="#">183-1-12-.10</a>  | amended  | Jan. 23, 2020 | Feb. 12   |
|  | <a href="#">183-1-12-.11</a> --- <a href="#">183-1-12-.20</a>  | adopted  | Jan. 23, 2020 | Feb. 12   |
|  | <a href="#">183-1-14-.02</a> , <a href="#">183-1-14-.11</a> , <a href="#">183-1-14-.12</a>   | amended  | Jan. 23, 2020 | Feb. 12   |
|  | <a href="#">183-1-14-.13</a>   | adopted  | Jan. 23, 2020 | Feb. 12   |
|  | <a href="#">183-1-15-.02</a>   | amended  | Jan. 23, 2020 | Feb. 12   |
| 189. RULES OF STATE ETHICS<br>COMMISSION             | <a href="#">189-2-.01</a>  | amended  | Jan. 13, 2020 | Feb. 2    |
|  | <a href="#">189-2-.11</a>  | adopted  | Jan. 13, 2020 | Feb. 2    |
| 195. GEORGIA BOARD FOR<br>PHYSICIAN WORKFORCE        | <a href="#">195-14-.01</a> , <a href="#">195-14-.02</a> ,<br><a href="#">195-14-.04</a> --- <a href="#">195-14-.06</a> , <a href="#">195-14-.08</a> , <a href="#">195-14-.10</a> | amended  | Jan. 27, 2020 | Feb. 16   |
| 300. RULES OF GEORGIA<br>DEPARTMENT OF LABOR         | <a href="#">300-2-2-.02</a>  | amended  | Jan. 24, 2020 | Feb. 13   |
|  | <a href="#">300-2-3-.01</a> --- <a href="#">300-2-3-.03</a>  | amended  | Jan. 24, 2020 | Feb. 13   |
|  | <a href="#">300-2-8-.03</a>  | amended  | Jan. 24, 2020 | Feb. 13   |
|  | <a href="#">300-9-2-.01</a>  | adopted  | Jan. 24, 2020 | Feb. 13   |
| 360. RULES OF GEORGIA<br>COMPOSITE MEDICAL BOARD     | <a href="#">360-13-.01</a>   | amended  | Jan. 28, 2020 | Feb. 17   |
|  | <a href="#">360-30-.01</a>   | repealed | Jan. 28, 2020 | Feb. 17   |
| 375. RULES OF DEPARTMENT OF<br>DRIVER SERVICES       | <a href="#">375-3-3-.06</a> , <a href="#">375-3-3-.15</a>  | repealed | Jan. 30, 2020 | Feb. 19   |
|  | <a href="#">375-3-7-.07</a>  | repealed | Jan. 30, 2020 | Feb. 19   |
| 560. RULES OF DEPARTMENT OF<br>REVENUE               | <a href="#">560-11-14-.01</a> , <a href="#">560-11-14-.10</a> , <a href="#">560-11-14-.12</a>  | amended  | Jan. 29, 2020 | Feb. 18   |

# Department 40. RULES OF GEORGIA DEPARTMENT OF AGRICULTURE

## Chapter 40-32. HEMP GROWERS AND PROCESSORS

### Subject 40-32-1. GENERAL PROVISIONS

#### 40-32-1-.01 Authority and Purpose of Rules

Pursuant to the authority vested in the Georgia Department of Agriculture under the Georgia Hemp Farming Act, O.C.G.A. § [2-23-1](#) et. seq., the purpose of these Rules is to establish the standards, practices, procedures, and requirements for growing and processing hemp in Georgia.

Cite as Ga. Comp. R. & Regs. R. 40-32-1-.01

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Authority and Purpose of Rules" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

#### 40-32-1-.02 Definitions

Words used in these Rules in the singular form will be deemed to impart the plural, and vice versa, as the case may demand. For the purposes of these Rules, unless the context otherwise requires, the following terms will be construed, respectively, to mean:

(a) "Acceptable hemp THC level" - when a laboratory tests a sample, it must report the delta-9 tetrahydrocannabinol content concentration level on a dry weight basis and the measurement of uncertainty. The acceptable hemp THC level is when the application of the measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution or range that includes 0.3% or less. For example, if the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis is 0.35% and the measurement of uncertainty is +/- 0.06%, the measured delta-9 tetrahydrocannabinol content concentration level on a dry weight basis for this sample ranges from 0.29% to 0.41%. Because 0.3% is within the distribution or range, the sample is within the acceptable hemp THC level for the purpose of compliance.

(b) "Agricultural Marketing Service" or "AMS" - the Agricultural Marketing Service of the United States Department of Agriculture.

(c) "Application" - the necessary and required written request which must be submitted to the Department by an Applicant, as required by the Department, and which includes, but may not be limited to, all requirements of O.C.G.A. §§ [2-5-1](#) through [2-5-4.1](#) as stated therein.

(d) "Applicant" - a person, or a person serving in an official capacity or as an agent who is authorized to sign for a business entity, who submits an application for a Hemp Grower License or a Hemp Processor Permit.

(e) "Commercial sale" - the sale of a product in the stream of commerce at retail, at wholesale, and online.

(f) "Commissioner" - the Georgia Commissioner of Agriculture.

(g) "Controlled Substances Act" or "CSA" - the federal Controlled Substances Act as codified in [21 U.S.C. 801](#) et seq.

(h) "Conviction" - for purposes of these Rules, means any plea of guilty or nolo contendere, or any finding of guilt, except when the finding of guilt is subsequently overturned on appeal, pardoned, or expunged. For purposes of these

Rules, a conviction is expunged when the conviction is removed from the individual's criminal history record and there are no legal disabilities or restrictions associated with the expunged conviction, other than the fact that the conviction may be used for sentencing purposes for subsequent convictions. In addition, where an individual is allowed to withdraw an original plea of guilty or nolo contendere and enter a plea of not guilty and the case is subsequently dismissed, the individual is no longer considered to have a conviction for purposes of this part.

- (i) "Corrective action plan" - a plan established by the Department for a Licensee or Permittee to correct negligent violations of or non-compliance with the Act or these Rules.
- (j) "Culpable mental state greater than negligence" - to act intentionally, knowingly, willfully, or recklessly.
- (k) "Cultivate" means to plant, water, grow, and harvest a plant or crop.
- (l) "Decarboxylated" - the completion of the chemical reaction that converts THC-acid (THC-A) into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of THC-acid.
- (m) "Decarboxylation" - the removal or elimination of carboxyl group from a molecule or organic compound.
- (n) "Delta-9 tetrahydrocannabinol" or "Delta-9 THC" - the primary psychoactive component of cannabis. For the purposes of this part, delta-9 THC and THC are interchangeable.
- (o) "Department" - the Georgia Department of Agriculture, its agent(s), or its designee(s).
- (p) "Drug Enforcement Administration" or "DEA" - the United States Drug Enforcement Administration.
- (q) "Dry weight basis" - the ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.
- (r) "Entity" - a corporation, joint stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization, including any such organization participating in the hemp production as a partner in a general partnership, a participant in a joint venture, or a participant in a similar organization.
- (s) "Farm Service Agency" or "FSA" - the Farm Service Agency of the United States Department of Agriculture.
- (t) "Gas chromatography" or "GC" - a type of chromatography in analytical chemistry used to separate, identify, and quantify each component in a mixture. GC relies on heat for separating and analyzing compounds that can be vaporized without decomposition.
- (u) "Georgia Hemp Farming Act" - the Georgia law authorizing the Department to regulate hemp growers and processors, as provided in O.C.G.A. § [2-23-1](#) et. seq.
- (v) "Geospatial location" or "GPS coordinates" - a location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.
- (w) "Grow site" - a contiguous lot, parcel, or tract of land identified in an approved Hemp Grower License application on which a Licensee cultivates or intends to cultivate hemp. A Grow Site may include greenhouses as well as land and buildings that are not used to cultivate hemp. Each lot, parcel, or tract of land separated by a barrier or buffer of at least twelve feet (12') in width will be considered a separate Grow Site.
- (x) "Handle" - to possess or store hemp plants for any period of time on premises owned, operated, or controlled by a person licensed to cultivate or process hemp, or to possess or store hemp plants in a vehicle for any period of time other than during the actual transport of such plants from the premises of a person licensed to cultivate or process

hemp to the premises of another licensed person; provided, however, that such term does not include possessing or storing finished hemp products.

(y) "Harvest lot" or "Lot" - a quantity of hemp, of the same variety, harvested in a distinct timeframe that is: (1) Cultivated in one contiguous production area within a grow site; or (2) Cultivated in a portion or portions of one contiguous production area within a grow site. Harvest lot does not include a quantity of hemp comprised of hemp grown in noncontiguous production areas.

(z) "Hemp" - the *Cannabis sativa* L. plant and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with the federally defined THC level for hemp or a lower level.

(aa) "Hemp Crop" - one (1) or more unprocessed hemp plant(s) or plant parts.

(bb) "Hemp Grower License" or "Grower License" - a license issued by the Department under the authority of the Georgia Hemp Farming Act authorizing a person to handle and cultivate hemp in the State of Georgia.

(cc) "Hemp Processor Permit" or "Processor Permit" - a permit issued by the Department under the authority of the Georgia Hemp Farming Act authorizing a person to handle and process hemp in the State of Georgia.

(dd) "Hemp Product" - all products with the federally defined THC level for hemp derived from, or made by, processing hemp plants or plant parts that are prepared in a form available for commercial sale, but not including food products infused with THC unless approved by the United States Food and Drug Administration.

(ee) "High-performance liquid chromatography" or "HPLC" - a type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. HPLC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds.

(ff) "Information sharing system" - the database mandated under the federal Agricultural Marketing Act of 1946 which allows USDA to share information collected under State, Tribal, and USDA plans with Federal, State, Tribal, and local law enforcement.

(gg) "Key participant" - a sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer and chief financial officer. This definition does not include non-executive managers such as farm, field, or shift managers.

(hh) "Law enforcement" or "Law enforcement agency" - any Federal, State, or local law enforcement agency.

(ii) "Licensee" - an individual or business entity possessing a Hemp Grower License issued by the Department under the authority of the Georgia Hemp Farming Act to handle and cultivate hemp in the State of Georgia.

(jj) "Measurement of Uncertainty" or "MU" - the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

(kk) "Negligence" - failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part.

(ll) "Permittee" - an individual or business entity possessing a Hemp Processor Permit issued by the Department under the authority of the Georgia Hemp Farming Act to handle and process hemp in the State of Georgia.

(mm) "Person" - a natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association, or other form of legal business entity, as well as a state or local government entity.

(nn) "Phytocannabinoid" - cannabinoid chemical compounds found in the cannabis plant, two of which are Delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD).

(oo) "Postdecarboxylation" - in the context of testing methodologies for THC concentration levels in hemp, means a value determined after the process of decarboxylation that determines the total potential delta-9 tetrahydrocannabinol content derived from the sum of the THC and THC-A content and reported on a dry weight basis. The postdecarboxylation value of THC can be calculated by using a chromatograph technique using heat, gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The postdecarboxylation value of THC can also be calculated by using a high-performance liquid chromatograph technique, which keeps the THC-A intact, and requires a conversion calculation of that THC-A to calculate total potential THC in a given sample. See the definition for decarboxylation.

(pp) "Process" or "processing" - converting an agricultural commodity into a marketable form.

(qq) "Product lot" - a specific quantity of finished hemp products having uniform character and quality within specified limits.

(rr) "Qualified Agricultural Producer" - a producer of agricultural products who meets one of the following criteria:

1. The person or entity is the owner or lessee of agricultural land or other real property from which \$5,000.00 or more of agricultural products in aggregate were produced and sold during the year, including payments from government sources;
2. The person or entity is in the business of performing agricultural operations and has provided \$5,000.00 of such services during the year;
3. The person or entity is in the business of producing long-term agricultural products from which there might not be annual income, including, but not limited to, timber, pulpwood, orchard crops, pecans, livestock, and horticultural or other multiyear agricultural or farm products. Applicants must demonstrate that sufficient volumes of such long-term agricultural products will be produced which have the capacity to generate in aggregate at least \$5,000.00 in annualized sales in the future; or
4. The person or entity must establish, to the satisfaction of the Commissioner of Agriculture, that the person or entity is actively engaged in the production of agricultural products and has or will have created sufficient volumes to generate in aggregate at least \$5,000.00 in annualized sales.

(ss) "Reverse distributor" - a person who is registered with the DEA in accordance with [21 CFR 1317.15](#) to dispose of marijuana under the Controlled Substances Act.

(tt) "Secretary" - the United States Secretary of Agriculture.

(uu) "USDA" - the United States Department of Agriculture.

(vv) "Variety" - a group of plants or an individual plant that exhibits distinctive observable physical characteristic(s) or has a distinct genetic composition.

(ww) "Volunteer cannabis plant" - any cannabis plant that: (a) Grows of its own accord from seeds or roots in the years following an intentionally planted cannabis crop; and (b) Is not intentionally planted.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-1-.02

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Definitions" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-1-.03 Compliance with Federal Law**

Nothing in these Rules will be construed as authorizing any person to violate any Federal law or regulation.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-1-.03

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Compliance with Federal Law" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-1-.04 Georgia Hemp Plan - Incorporation by Reference**

Pursuant to the requirements of O.C.G.A. § [2-23-11](#), the Georgia Department of Agriculture, in consultation with the Governor and Attorney General, has submitted to the Secretary of Agriculture of the United States a plan under which the Department intends to regulate hemp production in Georgia. Upon approval of the Georgia Hemp Plan, or an amended plan, by the Secretary of Agriculture, such plan will be deemed incorporated into these Rules by reference. The approved plan will be posted on the Department's website at [agr.georgia.gov](http://agr.georgia.gov).

**Cite as** Ga. Comp. R. & Regs. R. 40-32-1-.04

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Georgia Hemp Plan - Incorporation by Reference" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-1-.05 Consultation with the Georgia Bureau of Investigation**

Pursuant to the requirements of O.C.G.A. § [2-23-12](#), these Rules, which are necessary to implement the provisions of the Georgia Hemp Farming Act, have been developed in consultation with the Georgia Bureau of Investigation.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-1-.05

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Consultation with the Georgia Bureau of Investigation" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-1-.06 Severability**

If any provision of these Rules or the application thereof to any person or circumstance is held invalid for any reason, the invalidity shall not affect the other provisions or any other application of these Rules which can be given effect without the invalid provisions or application. To this end all provisions of these sections are declared to be severable.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-1-.06

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Severability" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

# **Department 40. RULES OF GEORGIA DEPARTMENT OF AGRICULTURE**

## **Chapter 40-32. HEMP GROWERS AND PROCESSORS**

### **Subject 40-32-2. HEMP GROWERS**

#### **40-32-2-.01 Application for Hemp Grower License**

(1) Any person desiring to cultivate and handle hemp at any location in Georgia must submit a complete and accurate Hemp Grower License Application online at the Department's website, [agr.georgia.gov](http://agr.georgia.gov).

(2) Any person producing or intending to produce hemp must have a valid Hemp Grower License prior to receiving, producing, cultivating, handling, or storing hemp. A valid license means that the license has been issued and is unexpired, unsuspended, and unrevoked.

(3) As part of the Hemp Grower License Application, each applicant must submit to the Department the following:

(a) An annual Hemp Grower License fee of \$50.00 per acre cultivated up to a maximum application fee of \$5,000.00;

1. The applicant must provide the maximum total acres of hemp intended to be cultivated in fields during the relevant licensing period.

2. Applicants cultivating hemp in greenhouses or other buildings or structures must identify the maximum number and size, in square footage, of greenhouses or other buildings or structures intended to be used for cultivation during the relevant licensing period.

3. The license fee will not be prorated for fractions of acres. Fractional acreage will be rounded up to the next whole number for fee calculation purposes.

4. Each greenhouse or other building or structure in which hemp is cultivated will be considered a separate acre for fee calculation purposes. Acreage calculations for each greenhouse or other building or structure will be determined on a 43,560 square-foot basis.

5. Any Licensee who cultivates more acres than that which is listed on the Hemp Grower License Application will be deemed to have violated their Hemp Grower License and will be subject to enforcement under the Georgia Hemp Farming Act and these Rules.

(b) Information sufficient to prove that the applicant is a qualified agricultural producer including, but not limited to, an acknowledgment and production, upon request, of at least one of the following:

1. Current Georgia Agriculture Tax Exemption Certification;

2. IRS schedule F form (Profit or Loss from Farming);

3. IRS form 4835 form (Farm Rental Income and Expenses);

4. IRS schedule E form (Supplemental Income and Loss);

5. IRS form 4797 form (Sales of Business Property);

6. IRS form 1065 form (U.S. Return of Partnership Income);

7. IRS form 1120 form (U.S. Corporation Income Tax Return);
8. IRS form 1120S (U.S. Income Tax Return for an S Corporation); or
9. Any tax returns, forms, sales receipts, or other information or documentation as may be requested or required by the Commissioner.

(c) Contact information including, but not limited to:

1. Name;
2. Street Address;
3. Mailing Address;
4. Telephone Number; and
5. Email Address.

(d) If the applicant is a business entity, information including, but not limited to:

1. Legal business name or trade name;
2. Business structure type;
3. Address of the principal business location;
4. Primary contact information;
5. Current Certificate of Existence obtained through the Georgia Secretary of State's Office;
6. Any required local business license(s);
7. Employer Identification Number (EIN); and
8. Name, title, and current primary contact information, including telephone number and email address, for each owner, key participant, and person holding a beneficial interest in the Hemp Grower License for which an application is being made.

(e) Information sufficient for locating fields and greenhouses to be used to cultivate and harvest hemp, specifically;

1. If hemp is cultivated or is intended to be cultivated in a field:

- (i) A legal description, obtained from the relevant county courthouse property records, of land on which hemp will be cultivated or handled;
- (ii) GPS coordinates provided in decimal of degrees and taken at the approximate center of each Grow Site; and
- (iii) An aerial map or photograph that clearly shows the boundaries and dimensions of each Grow Site in acres or square feet.

2. If hemp is cultivated or is intended to be cultivated in a greenhouse or other building or structure:

- (i) A legal description, obtained from the relevant county courthouse property records, of land on which hemp will be cultivated or handled;

- (ii) GPS coordinates provided in decimal of degrees and taken at the approximate entrance of the greenhouse or other building composing the Grow Site;
- (iii) The approximate dimension or square feet of the greenhouse or other building composing the Grow Site; and
- (iv) An aerial map or photograph that clearly shows the boundaries and dimensions of each Grow Site in acres or square feet.
- (f) Information sufficient for locating hemp storage facilities including, but not limited to:
  - 1. A legal description, obtained from the relevant county courthouse property records, of land on which hemp will be stored;
  - 2. GPS coordinates provided in decimal of degrees and taken at the approximate entrance of each storage facility;
  - 3. The approximate dimension or square feet of each storage facility; and
  - 4. An aerial map or photograph that clearly shows the boundaries and dimensions of each storage facility.
- (g) The name and contact information including, but not limited to, physical address, mailing address, telephone number, and e-mail address, of the Permittee(s) with whom the applicant has entered into or intends to enter into an agreement pursuant to O.C.G.A. § [2-23-7](#) and the affidavit(s) required by O.C.G.A. § [2-23-6](#);
- (h) Written consent allowing representatives of the Department, the Georgia Bureau of Investigation, and other federal, state, and local law enforcement agencies to enter all premises where hemp is being cultivated, harvested, or handled for the purpose of conducting physical inspections and ensuring compliance with the requirements of the Georgia Hemp Farming Act and these Rules;
- (i) A current criminal background check for each owner, key participant, and person holding a beneficial interest conducted by local law enforcement and dated within 60 days prior to the application submission date. A license application will not be considered complete without all required criminal background checks;
- (j) An acknowledgement of the Grower License Terms and Conditions;
- (k) A copy of the deed or lease for the Grow Site(s) property, whether it is a field or a greenhouse, along with copies of relevant easements or licenses as proof of legal authority to cultivate hemp on the Grow Site(s); and
- (l) Any other information, disclosure, or documents required to be submitted by Georgia or Federal law or regulation.
- (4) Except for the 2020 growing season, Hemp Grower Licenses will be issued on January 1 of each year.
- (5) Hemp Grower Licenses will expire on December 31 of each year unless suspended, cancelled, or revoked at an earlier date.
- (6) A current and valid Hemp Grower License may be renewed by submitting a renewal application, annual license fee, annual criminal background checks dated within 60 days prior to the renewal application submission date, and all other required information online at the Department's website, [agr.georgia.gov](http://agr.georgia.gov), by December 1 of each year.
- (7) Any person who materially falsifies any information contained in an application for a Hemp Grower License will be ineligible to receive a Hemp Grower License or otherwise participate in the Georgia Hemp Program.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.01

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Application for Hemp Grower License" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.02 Grower License Terms and Conditions**

Each Licensee must acknowledge and agree to the terms and conditions governing the Hemp Grower License which include, but are not limited to, the following:

- (a) Except for primary contact information or corrections of typographical errors approved by the Department, no alterations will be allowed to any Hemp Grower License Application or to any Grow Site once approved. Any changes to primary contact information must be submitted to the Department via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov) within ten (10) calendar days of any such change.
- (b) The Licensee must notify the Department, via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov), of any theft or loss of hemp or hemp materials, whether growing or not, within forty-eight (48) hours of the discovery of such theft or loss.
- (c) The Licensee must report any felony convictions or misdemeanor convictions relating to controlled substances under Georgia law or under Federal law to the Department, via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov), within five (5) calendar days of receiving notice of such conviction.
- (d) The Licensee must notify the Department, via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov), within ten (10) calendar days of the following:
  - 1. A disciplinary proceeding or enforcement action by another government entity that may affect the Licensee's business; and
  - 2. Temporary closures of more than thirty (30) calendar days or permanent closure of any Grow Site or storage facility.
- (e) Any information provided to the Department may be publicly disclosed in accordance with the Georgia Open Records Act (O.C.G.A. § [50-18-70](#) et. seq.) and may be provided to law enforcement agencies without further notice to the applicant.
- (f) A person with a state or federal felony conviction related to a controlled substance is subject to a 10-year ineligibility restriction on participating in the Georgia Hemp Program from the date of the conviction. An exception applies to a person who was lawfully growing Hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date. Each owner, key participant, and person holding a beneficial interest of the Licensee will be subject to the felony conviction restriction for purposes herein.
- (g) No person will be issued more than one Hemp Grower License, nor will any person be permitted to have a beneficial interest in more than one Hemp Grower License, regardless of the degree of such interest, as provided in O.C.G.A. § [2-23-5](#).
- (h) Hemp Grower Licenses cannot be sold, assigned, transferred, pledged, or otherwise disposed of, alienated, or encumbered to or by another person, business, individual, or entity.
- (i) The Licensee must have the legal right to cultivate hemp on the Grow Site(s) listed on the Hemp Grower License Application and must have the legal authority to grant the Department physical access to all land and buildings for inspection and sampling purposes. Legal authority includes, but is not limited to, clear title, necessary easements, necessary licenses, and/or current leases.
- (j) The Licensee must allow and fully cooperate with all required sampling, testing, audits, and inspections.
- (k) The Licensee must provide for a right of way or other access point allowing the Department and law enforcement agencies to access the licensed Grow Site(s).

- (l) The Licensee must maintain all records, documents, or information and make all reports within the applicable time frames as required in these Rules.
- (m) Hemp must not be cultivated, handled, harvested, or stored in any location that is not listed in the Hemp Grower License Application.
- (n) The Licensee must scout and monitor unlicensed fields for volunteer cannabis plants and destroy those volunteer cannabis plants for three (3) years past the last date of planting reported to the Department.
- (o) The Department will require forfeiture and destruction, without compensation, of plants located in an area that is not licensed by the Department as well as plants not accounted for in records required to be maintained by the Licensee.
- (p) In the event that a tested official sample exceeds the acceptable hemp THC level, the Licensee's entire crop with the same GPS coordinates will be destroyed in accordance with these Rules.
- (q) The Licensee must not handle, process, store, sell, transfer, ship, transport, deliver, distribute, or otherwise provide any cannabis that exceeds the acceptable hemp THC level. The Licensee must ensure that cannabis exceeding the acceptable hemp THC level does not enter the stream of commerce.
- (r) The Licensee must ensure that hemp and hemp plant material from one lot is not commingled with hemp or hemp plant material from other lots.
- (s) The Licensee must not ship, transport, deliver, or allow live hemp plants and materials produced by the Licensee to be shipped, transported, or otherwise delivered to unlicensed areas including, but not limited to, trade shows, county fairs, educational events, or other events.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.02

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Grower License Terms and Conditions" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.03 Grower Sampling Requirements**

- (1) Within 15 days prior to the anticipated harvest of any cannabis plants, the Licensee must have a Department-approved sampling agent collect samples from the flower material of such cannabis plants for delta-9 tetrahydrocannabinol concentration level testing.
- (2) Sampling will be conducted in accordance with the USDA's most current *Sampling Guidelines for Hemp Growing Facilities*, which will be made available on the Department's website at [agr.georgia.gov](http://agr.georgia.gov).
- (3) The method used for sampling from the flower material of the cannabis plant must be sufficient at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.
- (4) During a scheduled sample collection, the Licensee or an authorized representative of the Licensee must be present at the grow site.
- (5) The cannabis material to be collected for sampling will be determined by the Department-approved sampling agent.

(6) The Licensee will be responsible for paying all sampling fees. No compensation will be owed by the Department to the Licensee for any such sampling or for any samples collected by the Department-approved sampling agent.

(7) Only samples taken by a Department-approved sampling agent will be considered official samples.

(8) The Department-approved sampling agent(s) must be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants and material, whether growing or harvested, and all land, buildings, and other structures used for the cultivation, handling, or storage of all hemp and other cannabis plants, and all locations listed in the Hemp Grower License.

(9) A Licensee must not harvest any cannabis prior to samples being taken.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.03

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Grower Sampling Requirements" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

#### **40-32-2-.04 Grower Laboratory Testing Requirements**

(1) Standard testing procedures are specified for samples taken in accordance with the sampling procedures for the Georgia Hemp Program to measure the delta-9 tetrahydrocannabinol (THC) concentration levels of those samples on a dry weight basis.

(2) Analytical testing for purposes of detecting the concentration levels of delta-9 tetrahydrocannabinol (THC) must be conducted and reported by a laboratory registered with DEA to handle controlled substances under the Controlled Substances Act (CSA), [21 CFR part 1301.13](#).

(3) Analytical testing for purposes of detecting the concentration levels of delta-9 tetrahydrocannabinol (THC) must be conducted in accordance with the USDA's most current *Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp*, which will be made available on the Department's website at [agr.georgia.gov](http://agr.georgia.gov). Such testing must meet the following standards:

(a) Laboratory quality assurance must ensure the validity and reliability of test results;

(b) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(c) The demonstration of testing validity must ensure consistent, accurate analytical performance; and

(d) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this Rule.

(4) At a minimum, analytical testing of samples for delta-9 tetrahydrocannabinol concentration levels must use post-decarboxylation or other similarly reliable methods approved by the Secretary or Commissioner. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC) and the test result reflect the total available THC derived from the sum of the THC and THC-A content. Testing methodologies meeting the requirements of this Rule include, but are not limited to, gas or liquid chromatography with detection.

(5) The total delta-9 tetrahydrocannabinol concentration level must be determined and reported on a dry weight basis.

(6) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories must use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(7) Any sample test result exceeding the acceptable hemp THC level will be conclusive evidence that the lot represented by the sample is not in compliance with these Rules.

(8) Each Licensee must ensure that the DEA-registered laboratory conducting the analytical testing of the sample(s) from the Licensee's lots submits results for all tested samples to the Department via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov). The test results must be reported using the Department's "Grower Laboratory Test Results Report" form and must contain the following information for each sample tested:

- (a) Producer's license or authorization identifier;
- (b) Name of producer;
- (c) Business address of producer;
- (d) Lot identification number for the sample;
- (e) Name and DEA registration number of the laboratory;
- (f) Date of test and report;
- (g) Identification of a retest;
- (h) Measurement of uncertainty (MU); and
- (i) Test result.

(9) The Licensee will be responsible for paying all testing fees. No compensation will be owed by the Department to the Licensee for any such testing.

(10) A Licensee must not transfer, transport, or otherwise distribute any lot of cannabis prior to receiving analytical testing results verifying that the lot does not exceed the acceptable hemp THC level.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.04

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Grower Laboratory Testing Requirements" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.05 Grower Responsibilities and Restrictions**

- (1) The Licensee must harvest the crop not more than fifteen (15) days following the date of sample collection.
- (2) If the Licensee fails to complete harvest within fifteen (15) days of sample collection, a secondary pre-harvest sample of the lot will be required to be submitted for testing.
- (3) Harvested lots of hemp plants must not be commingled with other harvested lots or other material without prior written permission from the Department.
- (4) Only lots that meet the acceptable hemp THC level may enter the stream of commerce.
- (5) Any lot with an official sample test result exceeding the acceptable hemp THC level must not be further handled, processed, or enter the stream of commerce, and the Licensee must ensure the lot is disposed of in accordance with these Rules.

(6) Any Licensee may request additional testing if it is believed that the original delta-9 tetrahydrocannabinol concentration level test results were in error.

(7) A Licensee must not:

(a) Cultivate or handle hemp on any Grow Site not listed on the Hemp Grower License Application and must take immediate steps to prevent the inadvertent growth of hemp outside of the authorized Grow Site(s);

(b) Cultivate or handle any cannabis that is not hemp;

(c) Cultivate or handle hemp in any structure that is used for residential purposes;

(d) Fail to keep hemp physically separated from other crops unless prior approval is obtained in writing from the Department;

(e) Allow unsupervised public access to hemp or hemp Grow Sites; or

(f) Cultivate or handle hemp on property owned by, leased from, or previously submitted in a Hemp Grower License Application by any person who is ineligible for, was terminated from, or was denied admission to the program for failure to obtain an acceptable criminal history report or for violations of the Georgia Hemp Farming Act or these Rules.

(2) The Licensee must post signage at the entrance to each Grow Site that is one (1) acre or less in size as well as at locations where Grow Sites are visible to public roadways in a manner that would reasonably be expected to be seen by a person in the area. The signage must be at least three feet (3') in length and two feet (2') in height or the maximum allowable size for signage pursuant to applicable local ordinances, which is smaller, and must include the following information:

(a) The statement, "Georgia Department of Agriculture Licensed Hemp Grower";

(b) The name of the Licensee;

(c) The Georgia Department of Agriculture Hemp Grower License number; and

(d) The Department's telephone number, (404) 656-3600.

(3) The Licensee must comply with all applicable local, state, and federal laws, rules, regulations, and ordinances at all times.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.05

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Grower Responsibilities and Restrictions" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

#### **40-32-2-.06 Disposal of Non-Compliant Cannabis**

(1) Cannabis exceeding the acceptable hemp THC level constitutes marijuana, a schedule I controlled substance under Georgia law and federal law.

(2) Marijuana must be disposed of in accordance with the CSA and DEA regulations found at [21 CFR 1317.15](#) by a reverse distributor.

(3) The Licensee must immediately notify the Department via email to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov) any time analytical testing determines that a lot has exceeded the acceptable hemp THC level.

(4) Upon notice and confirmation that a lot has exceeded the acceptable hemp THC level, the Department will issue an Order of Disposal requiring the entire crop and all plant material to be disposed within a reasonable time to be determined by the Department.

(5) The Licensee will be responsible for arranging disposal through a reverse distributor.

(6) The Licensee will be responsible for all costs and fees associated with the disposal of cannabis exceeding the acceptable hemp THC level. No compensation will be owed by the Department to the Licensee for any such disposal.

(7) Cannabis subject to disposal must not be removed from the Grow Site or from any other area where such cannabis is being handled or stored.

(8) Within 30 days of the date of completion of disposal, the Licensee must submit a "Disposal Report" form to the Department, which must contain the following information:

(a) Name and address of the Licensee;

(b) Hemp Grower License number;

(c) Geospatial location, including location type, or other valid land descriptor, for the production area subject to disposal;

(d) Information on the reverse distributor agent handling the disposal;

(e) Total acreage disposed;

(f) Date of completion of disposal;

(g) Signature of the Licensee; and

(h) Reverse distributor agent certification of completion of the disposal.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.06

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Disposal of Non-Compliant Cannabis" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.07 Transportation Requirements**

(1) All hemp being shipped, transported, or otherwise delivered into, within, or through the State of Georgia must be accompanied by documentation sufficient to prove:

(a) The hemp being shipped, transported, or delivered was lawfully produced under a State or Tribal hemp plan approved by the USDA, under a hemp license issued by USDA, or under [7 U.S.C. 5940](#) through the State or territory of the Indian Tribe, as applicable; and

(b) The hemp being shipped, transported, or delivered does not exceed the acceptable hemp THC level.

(2) Any person shipping, transporting, or delivering hemp must also carry a bill of lading that includes the following information:

(a) Name and address of the owner of the hemp;

- (b) Point of origin;
  - (c) Point of delivery, including name and address;
  - (d) Kind and quantity of packages or, if in bulk, the total quantity of hemp in the shipment; and
  - (e) Date of shipment.
- (3) The person shipping, transporting, or delivering hemp must act in compliance with all Georgia and Federal laws and regulations.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.07

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Transportation Requirements" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.08 Storage of Hemp**

- (1) A Licensee may store hemp cultivated by said Licensee provided:
- (a) The Licensee identifies each storage facility on the Hemp Grower License Application;
  - (b) The Licensee maintains complete and accurate records detailing the harvest lot(s), including amount being stored at each storage facility. Harvest lots in storage must be separated in such a manner that maintains the unique identity of each harvest lot stored at the storage facility;
    - 1. In the event that a tested official sample of hemp held at a storage facility exceeds the acceptable hemp THC level, all comingled hemp held at the storage facility will be promptly destroyed in accordance with these Rules.
  - (c) The storage facility is owned or leased by the Licensee; and
  - (d) The storage facility is secured with physical containment and reasonable security measures.
- (2) No Licensee may warehouse or otherwise store hemp that is not owned by the Licensee.
- (3) All storage area(s) will be subject to inspection by Department officials.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.08

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Storage of Hemp" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.09 Pesticide Use**

- (1) Any Licensee who uses a pesticide on hemp must comply with all Georgia laws and regulations pertaining to applications of pesticides including, but not limited to, licensing requirements.
- (2) Licensees must not apply pesticides to hemp in violation of the product label.
- (3) A Licensee who uses a pesticide on a site where hemp will be planted must comply with the longest of any planting restriction interval on the product label prior to planting the hemp.

(4) The Department may perform random pesticide testing or may perform for-cause testing if the Department has reason to believe that a pesticide may have been applied to hemp in violation of the product label.

(5) Hemp seeds, plants, and materials bearing pesticide residue in violation of the pesticide label may be subject to forfeiture or destruction without compensation.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.09

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Pesticide Use" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

## **40-32-2-.10 Recordkeeping and Reporting Requirements**

### (1) Licensee Recordkeeping and Reporting

(a) Licensees must maintain records of all hemp plants acquired, produced, handled, or disposed of as will substantiate any and all reports required by the Department.

(b) All records must be made available for inspection by the Department during reasonable business hours. The such records including, but are not limited to, the following:

1. Records regarding acquisition of hemp;
2. Records regarding all written agreements with Permittees governing their business relationship;
3. Records regarding production and handling of hemp;
4. Records regarding hemp sampling and testing analyses;
5. Records regarding storage of hemp;
6. Records regarding the transfer and disposal of hemp; and
7. Records regarding destruction and disposal of all cannabis plants exceeding the acceptable hemp THC level.

### (c) Annual Report

1. Each Licensee must submit an annual report to the Department. The report form must be submitted by November 30 of each year and contain the following information:

- (i) Licensee's name;
- (ii) Licensee's address;
- (iii) Georgia Hemp Grower License Number;
- (iv) Street address and geospatial location of each lot, greenhouse, building, or site where hemp will be produced;
- (v) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp; and
- (vi) Total acreage of hemp planted, harvested, and disposed.

2. The Department will report all information collected in the Annual Report to AMS as required by USDA.

(d) Reporting to FSA Required

1. All Licensees must report hemp crop acreage with FSA and must provide, at minimum, the following information to FSA:

(i) Hemp crop acreage;

(ii) Total acreage of hemp planted, harvested, and disposed;

(iii) Georgia Hemp Grower License Number;

(iv) Street address;

(v) Geospatial location of each lot, greenhouse, building, or site where hemp will be produced. All locations where hemp is produced must be reported to FSA; and

(vi) Acreage of greenhouse or indoor square footage dedicated to the production of hemp.

(e) All records and reports must be kept and maintained by the Licensee for not less than three calendar years and in a manner such that they can be readily provided to the Department upon request.

(2) Department Recordkeeping and Reporting

(a) The Department will maintain all relevant records and information regarding Licensees and land on which hemp is produced in Georgia, including a legal description of the land, for a period of not less than three calendar years.

(b) The Department will collect, maintain, and report to USDA via fax, certified mail, email, or other method deemed acceptable by USDA the following contact and real-time information for each Licensee in Georgia:

1. The contact information of each Licensee collected pursuant to Rule [40-32-2-.01](#).

2. A legal description of the land on which hemp is grown including its geospatial location; and

3. The status of licensed growers (and any changes) and Hemp Grower License number of each hemp grower.

(c) By the first of each month, and not more than thirty (30) days after receipt, the Department will provide the following information to the United States Secretary of Agriculture or the Secretary's designee in a format that is compatible with USDA's Information Sharing System whenever possible. If the first of the month falls on a weekend or holiday, the report will be submitted by the first business day following the due date:

1. Hemp Grower Report, which will contain the following:

(i) For each new Licensee who is an individual and is licensed under the Georgia Hemp Plan, the report will include the full name of the individual; Georgia Hemp Grower License number; business address; telephone number; email address (if available); the legal description of the land on which the Licensee will produce hemp including, to the extent practicable, its geospatial location; and the scope of activity authorized;

(ii) For each new Licensee that is an entity and is licensed under the Georgia Hemp Plan, the report will include the full name of the entity; the principal business location address; EIN number; Georgia Hemp Grower License number; the full name, title, and email address (if available) of each person for whom the entity is required to submit a criminal history record report; the legal description of the land on which the Licensee will produce hemp including, to the extent practicable, its geospatial location; and the scope of activity authorized;

(iii) For each Licensee that was included in a previous report and whose reported information has changed, the report will include the previously reported information and the new information;

- (iv) The status of each hemp grower's license;
- (v) The period covered by the report; and
- (vi) Indication that there were no changes during the current reporting cycle, if applicable.

2. Hemp Disposal Report, which will contain the following:

- (i) Name and contact information of the Licensee;
- (ii) Hemp Grower License number;
- (iii) Location information, such as lot number, location type, and geospatial location or other location descriptor for the production area subject to disposal;
- (iv) A copy of the respective test results.
- (v) Information on the agent handling the disposal;
- (vi) Disposal completion date; and
- (vii) Total acreage disposed.

(d) Annual Report

1. The Department will submit an annual report to USDA. The report form will be submitted by December 15 of each year and contain the following information:

- (i) Total planted acreage;
- (ii) Total harvested acreage; and
- (iii) Total acreage disposed.

(e) Test Results Report

1. The Department will promptly notify USDA by certified mail or electronically of any occurrence of cannabis plants or plant material that do not meet the definition of hemp and will attach copies of analytical test results as well as records demonstrating appropriate disposal of all of those plants and materials in the lot from which the representative samples were taken.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.10

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Recordkeeping and Reporting Requirements" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-2-.11 Hemp Grower Compliance Inspections**

- (1) Licensees may be subject to annual compliance inspections.
- (2) The Licensee's operational procedures, documentation, recordkeeping, and other practices may be verified during the compliance inspection.

(3) The Department may assess whether required reports, records, and documentation are being properly maintained and may assess accuracy and completeness.

(4) If during a compliance inspection the Department determines that the Licensee is not in compliance with the Georgia Hemp Farming Act or these Rules, the Department will require a Corrective Action Plan. The Licensee's implementation of a Corrective Action Plan will be reviewed by the Department during future compliance inspections.

(5) Compliance inspections may be unannounced and conducted at any time during regular business hours. The Department will have complete and unrestricted access to all hemp plants, material, and seeds, whether growing or harvested, as well as to all land, buildings, and other structures used for the cultivation, handling, or storage of hemp. The Department will also have full access to any and all records, documents, and information required to be kept and maintained in accordance with these Rules.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.11

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Hemp Grower Compliance Inspections" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

#### **40-32-2-.12 Violations and Enforcement**

(1) Violations include, but are not limited to, the following:

- (a) Cultivating or handling hemp without a Hemp Grower License from the Department;
- (b) Cultivating or handling any cannabis that is not hemp;
- (c) Cultivating hemp that exceeds the acceptable hemp THC level;
- (d) Selling, transferring, shipping, transporting, delivering, distributing, or otherwise providing hemp that exceeds the acceptable hemp THC level;
- (e) Cultivating or handling hemp on a site not approved by the Department as part of the Hemp Grower License;
- (f) Allowing unsupervised public access to hemp growing or handling areas, including storage areas;
- (g) Denying any Department or law enforcement official access for compliance, sampling, or inspection purposes;
- (h) Failure to keep and maintain any records, documents, or information required by these Rules;
- (i) Failure to make any timely report required by these Rules;
- (j) Failure to comply with any transportation requirement established by these Rules;
- (k) Failure to comply with any of the Grower Responsibilities and Restrictions;
- (l) Failure to comply with any of the Grower License Term and Conditions; and
- (m) Failure to comply with, or any violation of, any other provision of the Georgia Hemp Farming Act or these Rules.

(2) A violation of the Georgia Hemp Farming Act or these Rules will be subject to enforcement in accordance with O.C.G.A. § [2-23-10](#).

(a) In the event the Department determines that a Licensee has negligently violated the Georgia Hemp Farming Act or these Rules, then the Department will issue a Corrective Action Plan to said Licensee.

1. The Corrective Action Plan will include, but may not be limited to:

(i) A reasonable date by which the Licensee must correct the negligent violation, which may include destruction of hemp crops in accordance with these Rules;

(ii) A requirement that the Licensee must periodically report to the Commissioner on the compliance status of the Licensee with the Corrective Action Plan for a period of not less than two (2) years after the violation; and

(iii) Any and all reasonable steps the Department deems necessary and proper to address the negligent violation(s).

2. Licensees do not commit a negligent violation if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a delta-9 tetrahydrocannabinol concentration of more than 0.5 percent on a dry weight basis.

3. The Department will monitor and conduct any and all inspections necessary to determine if the Corrective Action Plan has been implemented as required.

(b) If the Commissioner determines that a Licensee has violated the Georgia Hemp Farming Act or these Rules with a culpable mental state greater than negligence, the Commissioner will immediately report the Licensee to the United States Attorney General and the Georgia Attorney General, and such violations will be subject to enforcement in accordance with applicable law.

(c) Persons who violate the Georgia Hemp Farming Act or these Rules are subject to enforcement in accordance with the Georgia Hemp Farming Act, these Rules, and other applicable state law.

(d) Violations of the Georgia Hemp Farming Act or these Rules may constitute a public nuisance under Georgia law, and civil enforcement may result.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-2-.12

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Violations and Enforcement" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

# **Department 40. RULES OF GEORGIA DEPARTMENT OF AGRICULTURE**

## **Chapter 40-32. HEMP GROWERS AND PROCESSORS**

### **Subject 40-32-3. HEMP PROCESSORS**

#### **40-32-3-.01 Application for Hemp Processor Permit**

(1) Any person desiring to process and handle hemp at any location in Georgia must submit a complete and accurate Hemp Processor Permit Application online at the Department's website, [agr.georgia.gov](http://agr.georgia.gov).

(2) Any person processing or intending to process hemp must have a valid Hemp Processor Permit prior to receiving, processing, handling, or storing hemp. A valid permit means the permit has been issued and is unexpired, unsuspended, and unrevoked.

(3) As part of the Hemp Processor Permit Application, each applicant must submit to the Department the following:

(a) An initial annual Hemp Processor Permit fee of \$25,000.00;

(b) A surety bond in the amount of \$100,000.00 issued by a surety company authorized by law to do business in Georgia pursuant to a current certificate of authority to transact surety business by the Commissioner of Insurance;

(c) Information regarding the applicant's business including, but not limited to:

1. Legal business name or trade name;

2. Business structure type;

3. Address of the principal business location;

4. Primary contact information;

5. Current Certificate of Existence obtained through the Georgia Secretary of State's Office;

6. Any required local business license(s);

7. Employer Identification Number (EIN); and

8. Name, title, and current primary contact information, including telephone number and email address, for each owner, key participant, and person holding a beneficial interest in the Hemp Processor Permit for which an application is being made.

(d) A legal description, obtained from the relevant county courthouse property records, for property on which each processing or handling facility is located;

(e) GPS coordinates provided in decimal of degrees and taken at the approximate entrance of each facility;

(f) The approximate dimension or square feet of each facility;

(g) An aerial map or photograph of the processing facilities showing clear boundaries of each facility;

(h) Information sufficient for locating hemp storage facilities including, but not limited to:

1. A legal description, obtained from the relevant county courthouse property records, for property on which each storage facility is located;
  2. GPS coordinates provided in decimal of degrees and taken at the approximate entrance of each storage facility;
  3. The approximate dimension or square feet of each storage facility; and
  4. An aerial map or photograph that clearly shows the boundaries and dimensions of each storage facility.
- (i) A description of all hemp products to be produced as well as an estimate of the volume of each such product projected to be produced;
  - (j) A statement of the intended end use and/or disposal plan for all parts of hemp plants and hemp material received for processing;
  - (k) Affidavits of the applicant and every Licensee with whom such applicant has entered into a written agreement pursuant to O.C.G.A. § [2-23-7](#) in which both parties swear that they have entered into or intend to enter into such an agreement;
  - (l) Written consent, allowing representatives of the Department, the Georgia Bureau of Investigation, and other affected state and local law enforcement agencies to enter all premises where hemp is being processed or handled for the purpose of conducting physical inspections and ensuring compliance with the requirements of the Georgia Hemp Farming Act and these Rules;
  - (m) A current criminal background check for each owner, key participant, and person holding a beneficial interest conducted by local law enforcement and dated within 60 days prior to the application submission date. A permit application will not be considered complete without all required criminal background checks;
  - (n) An acknowledgment of the Processor Permit Terms and Conditions; and
  - (o) Any other information, disclosure, or documents required to be submitted by Georgia or Federal law or regulation.
- (4) Except for the 2020 growing season, Hemp Processor Permits will be issued on January 1 of each year.
  - (5) After the first full calendar year of holding a Hemp Processor Permit, a Permittee will be entitled to an automatic permit renewal annually upon timely submission of a permit fee of \$10,000.00 per year as well as annual criminal background checks, so long as no administrative action has been taken by the Department against the Permittee and provided the information in the Permit application is unchanged.
    - (a) Renewal fees and annual criminal background checks dated within 60 days prior to the submission date must be submitted by December 1 of each year. Permits will expire on December 31 of each year if renewal fees are not timely submitted as required hereunder.
    - (6) If the information in the original Permit application is no longer accurate, the Permittee must submit a new permit application to the Department.
    - (7) Any person who materially falsifies any information contained in an application for a Hemp Processor Permit will be ineligible to receive a Hemp Processor Permit or otherwise participate in the Georgia Hemp Program.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.01

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Application for Hemp Processor Permit" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.02 Processor Permit Terms and Conditions**

Each Permittee must acknowledge and agree to the terms and conditions governing the Hemp Processor Permit which include, but are not limited to, the following:

- (a) Except for primary contact information or corrections of typographical errors approved by the Department, no alterations will be allowed to any Hemp Processor Permit Application once approved. Any changes to primary contact information must be reported to the Department within ten (10) calendar days of the change.
- (b) The Permittee must notify the Department, via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov), of any theft or loss of hemp or hemp products within forty-eight (48) hours of discovery of such theft or loss.
- (c) The applicant and/or Permittee must report any felony convictions or misdemeanor convictions relating to controlled substances under Georgia law or under Federal law to the Department, via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov), within five (5) calendar days of receiving notice of such conviction.
- (d) The applicant or Permittee must notify the Department in writing within ten (10) calendar days of the following:
  - 1. A disciplinary proceeding or enforcement action by another government entity that may affect the Permittee's business; and
  - 2. Temporary closures of more than thirty (30) days or permanent closure of any processing or storage facility.
- (e) Any information provided to the Department may be publicly disclosed in accordance with the Georgia Open Records Act (O.C.G.A. § [50-18-70](#) et. seq.) and may be provided to law enforcement agencies without further notice to the applicant.
- (f) A person with a state or federal felony conviction related to a controlled substance is subject to a 10-year ineligibility restriction on participating in the Georgia Hemp Program from the date of the conviction. An exception applies to a person who was lawfully growing Hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date. Each owner, key participant, and person holding a beneficial interest of the Permittee will be subject to the felony conviction restriction for purposes herein.
- (g) Issuance of a Hemp Processor Permit will be conditioned upon the applicant's compliance with O.C.G.A. § [2-23-7](#) prior to initiating hemp processing activities.
- (h) A Permittee may also apply for and be issued no more than one Hemp Grower License. Any person holding both a Hemp Processor Permit and a Hemp Grower License must comply with Georgia Rules governing both Licensees and Permittees.
- (i) No person will be issued more than one Hemp Processor Permit, nor will any person be permitted to have a beneficial interest in more than one Hemp Processor Permit, regardless of the degree of such interest, as provided in O.C.G.A. § [2-23-5](#).
- (j) Hemp Processor Permits cannot be sold, assigned, transferred, pledged, or otherwise disposed of, alienated, or encumbered to or by another person, business, individual, or entity.
- (k) The Permittee must only process hemp at facilities identified in the Hemp Processor Permit Application and must have the legal authority to grant the Department access to any and all such facilities for inspection and sampling.
- (l) The Permittee must allow and fully cooperate with all required inspections and sampling.

(m) The Permittee must maintain all records and information and make all reports within the applicable time frames as required in these Rules.

(n) The Permittee must only accept for processing hemp that was lawfully produced under a State or Tribal hemp plan approved by the USDA, under a hemp license issued by USDA, or under [7 U.S.C. 5940](#) through the State or territory of the Indian Tribe, as applicable.

(o) The Permittee must not handle, process, store, sell, transfer, ship, transport, deliver, distribute, or otherwise provide any cannabis or cannabis product that exceeds the acceptable hemp THC level. The Permittee must ensure that cannabis or cannabis products exceeding the acceptable hemp THC level do not enter the stream of commerce.

(p) The Department will require forfeiture and destruction, without compensation, of hemp discovered at a processing facility for which records are not available to prove that said hemp was received from a Licensee or from a state with a plan to regulate hemp production that is approved by the USDA Secretary of Agriculture or otherwise in accordance with regulations promulgated by the USDA. Any hemp comingled with such hemp for which records are not available will also be subject to destruction.

(q) In the event that a tested official sample exceeds the acceptable hemp THC level, the Department will require all related hemp products be disposed by a reverse distributor without compensation to the Permittee and under the supervision of local law enforcement.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.02

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Processor Permit Terms and Conditions" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.03 Processor Sampling**

(1) Hemp products are subject to sampling by a Department-approved sampling agent for delta-9 tetrahydrocannabinol concentration level testing. The frequency of sampling and number of hemp products sampled for such testing will be determined by the Department.

(2) Sampling will be conducted in accordance with the Department's most current *Sampling and Testing Guidelines for Hemp Processing Facilities*, which will be made available on the Department's website at [agr.georgia.gov](http://agr.georgia.gov).

(3) The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the product lot.

(4) During a scheduled sample collection, the Permittee or an authorized representative of the Permittee must be present at the facility.

(5) The Permittee will be responsible for paying all sampling fees. No compensation will be owed by the Department to the Permittee for any such sampling or for any samples collected by the Department-approved sampling agent.

(6) Only samples taken by a Department-approved sampling agent will be considered official samples.

(7) The Department-approved sampling agent(s) must be provided with complete and unrestricted access during business hours to all hemp, hemp products, land, buildings and other structures used for the processing, handling, and storing of hemp and hemp products. The Department must also be provided with complete and unrestricted access to any and all records, documents, and information required to be kept and maintained in accordance with these Rules.

(8) A Permittee must not transfer, transport, or otherwise distribute hemp products from a sampled product lot prior to receiving analytical testing results verifying that the product lot sampled does not exceed the acceptable hemp THC level.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.03

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Processor Sampling" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.04 Processor Laboratory Testing**

(1) Standard testing procedures are specified for samples taken to measure the delta-9 tetrahydrocannabinol (THC) concentration levels of those samples.

(2) Analytical testing for purposes of detecting the concentration levels of delta-9 tetrahydrocannabinol (THC) must be conducted and reported by a laboratory registered with DEA to handle controlled substances under the Controlled Substances Act (CSA), [21 CFR part 1301.13](#).

(3) Analytical testing for purposes of detecting the concentration levels of delta-9 tetrahydrocannabinol (THC) must be conducted in accordance with the Department's *Sampling and Testing Guidelines for Hemp Processing Facilities*, which will be made available on the Department's website at [agr.georgia.gov](http://agr.georgia.gov). Such testing must meet the following standards:

(a) Laboratory quality assurance must ensure the validity and reliability of test results;

(b) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(c) The demonstration of testing validity must ensure consistent, accurate analytical performance; and

(d) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this Rule.

(4) At a minimum, analytical testing of samples for delta-9 tetrahydrocannabinol concentration levels must use post-decarboxylation or other similarly reliable methods approved by the Secretary or Commissioner. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC) and the test result reflect the total available THC derived from the sum of the THC and THC-A content. Testing methodologies meeting the requirements of this paragraph include, but are not limited to, gas or liquid chromatography with detection.

(5) The total delta-9 tetrahydrocannabinol concentration level must be determined and reported. Additionally, measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories must use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(6) Any sample test result exceeding the acceptable hemp THC level will be conclusive evidence that the product lot represented by the sample is not in compliance with these Rules.

(7) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories must use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(8) Each Processor must ensure that the DEA-registered laboratory conducting the analytical testing of the sample(s) from the Processor's product lots submits results for all tested samples to the Department via e-mail to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov). The test results must be reported using the Department's "Processor Laboratory Test Results Report" form and must contain the following information for each sample tested:

- (a) Georgia Processor Permit number;
  - (b) Name of Processor;
  - (c) Business address of Processor;
  - (d) Lot identification number for the sample;
  - (e) Name and DEA registration number of the laboratory;
  - (f) Date of test and report;
  - (g) Identification of a retest;
  - (h) Measurement of uncertainty (MU); and
  - (i) Test result.
- (9) The Permittee will be responsible for paying all testing fees. No compensation will be owed by the Department to the Permittee for any such testing.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.04

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Processor Laboratory Testing" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.05 Permittee Restrictions**

- (1) A Permittee must not:
- (a) Process or handle hemp on any site not listed on the Hemp Processor Permit application;
  - (b) Process or handle any cannabis that is not hemp;
  - (c) Sell, transfer, ship, transport, deliver, distribute, or otherwise provide hemp products that exceed the acceptable hemp THC level;
  - (d) Process or handle hemp or hemp products in any structure that is used for residential purposes;
  - (e) Process hemp with other products. Hemp must be processed separately from other products unless otherwise authorized in writing by the Department;
  - (f) Store hemp products with other products. Hemp products must be physically stored separately from other products at a processing or storage facility unless otherwise authorized in writing by the Department;
  - (g) Allow unsupervised public access to hemp or hemp processing and storage facilities; or
  - (h) Process or handle hemp on property owned by, leased from, or previously submitted in a permit application by any person who is ineligible for, was terminated from, or was denied admission to the program for failure to obtain an acceptable criminal background check or for violations of the Georgia Hemp Farming Act or these Rules.
- (2) The Permittee must comply with all applicable local, state, and federal laws, rules, regulations, and ordinances at all times including, but not limited to, the federal Food Drug and Cosmetic Act, 21 U.S.C. Chapter 9, and all laws, rules, regulations, and ordinances relating to product development, product manufacturing, consumer safety, and public health.

Cite as Ga. Comp. R. & Regs. R. 40-32-3-.05

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Permittee Restrictions" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.06 Disposal of Non-Compliant Cannabis Products**

(1) Cannabis products exceeding the acceptable hemp THC level constitute marijuana, a schedule I controlled substance under Georgia law and federal law.

(2) Cannabis products exceeding the acceptable hemp THC level must be disposed of in accordance with the CSA and DEA regulations found at [21 CFR 1317.15](#) by a reverse distributor and in the presence of local law enforcement.

(3) The Permittee must immediately notify the Department via email to [hemp@agr.georgia.gov](mailto:hemp@agr.georgia.gov) any time analytical testing determines that cannabis products exceed the acceptable hemp THC level.

(4) Upon notice and confirmation that a cannabis product has exceeded the acceptable hemp THC level, the Department will issue an Order of Disposal requiring all related cannabis products to be disposed within a reasonable time to be determined by the Department.

(5) The Permittee will be responsible for arranging disposal through a reverse distributor. The Permittee will also be responsible for ensuring that local law enforcement is present to supervise such disposal.

(6) The Permittee will be responsible for all costs and fees associated with the disposal of cannabis exceeding the acceptable hemp THC level. No compensation will be owed by the Department to the Permittee for any such disposal.

(7) Cannabis products subject to disposal must not be removed from the permitted facility or from any other area where such cannabis is being processed, handled, or stored.

(8) Within 30 days of the date of completion of disposal, the Processor must submit a "Disposal Report" form to the Department, which must contain the following information:

- (a) Name and address of the Permittee;
- (b) Georgia Processor Permit number;
- (c) Information on the reverse distributor agent handling the disposal.
- (d) Date of completion of disposal;
- (e) Signature of the Permittee;
- (f) Signature of local law enforcement agent; and
- (g) Reverse distributor certification of completion of the disposal.

Cite as Ga. Comp. R. & Regs. R. 40-32-3-.06

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Disposal of Non-Compliant Cannabis Products" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.07 Transportation Requirements**

(1) All hemp products being shipped into or transported within or through the State of Georgia must be accompanied by documentation sufficient to prove that the hemp products being shipped or transported were produced from hemp that was lawfully produced under a State or Tribal hemp plan approved by the USDA, under a hemp license issued by USDA, or under [7 U.S.C. 5940](#) through the State or territory of the Indian Tribe, as applicable.

(2) Any person transporting hemp products must also carry a bill of lading that includes the following information:

(a) Name and address of the owner of the hemp products;

(b) Point of origin;

(c) Point of delivery, including name and address;

(d) Kind and quantity of packages or, if in bulk, the total quantity of hemp products in the shipment; and

(e) Date of shipment.

(3) The person transporting hemp products must act in compliance with all Georgia and Federal laws and regulations.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.07

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Transportation Requirements" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.08 Storage of Hemp**

(1) A Permittee may store hemp obtained from licensed growers and/or processed by said Permittee provided:

(a) The Permittee identifies each storage facility on the Hemp Processor Permit Application;

(b) The Permittee maintains complete and accurate records detailing the licensed growers from whom hemp at each storage facility was received, varieties stored at each storage facility, and amount of each hemp variety stored at each storage facility. Product lots in storage must be separated in such a manner that maintains the unique identity of each product lot stored at the storage facility;

1. In the event analytical testing determines that an official sample of hemp or hemp products held at a storage facility exceeds the acceptable hemp THC level, all comingled hemp or hemp products held at the storage facility must be promptly disposed of in accordance with the CSA and DEA regulations found at [21 CFR 1317.15](#) by a reverse distributor and in the presence of local law enforcement.

(c) The storage facility is owned or leased by the Permittee; and

(d) The storage facility is secured with physical containment and reasonable security measures.

(2) No Permittee may warehouse or otherwise store hemp that is not owned by the Permittee.

(3) All storage area(s) will be subject to inspection by the Department.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.08

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Storage of Hemp" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.09 Recordkeeping Requirements**

(1) Permittees must keep and maintain copies of all written agreements with licensed growers, including growers holding a Georgia Hemp Grower License as well as growers licensed by the USDA or authorized to produce hemp under other USDA approved state or tribal hemp plans, governing their business relationship.

(2) Permittees must keep and maintain the following records:

(a) Hemp intake records, which include:

1. Name, location, and license number (Georgia Hemp Grower License number or other valid hemp grower identification number) for each grower from whom the Permittee accepts hemp for processing;
2. The date(s) on which hemp is received from each licensed grower;
3. Copies of analytical testing results confirming that each lot of hemp received for processing does not exceed the acceptable hemp THC level;
4. The amount of each variety received from each licensed grower; and
5. The hemp products for which each variety of hemp received from each licensed grower will be used.

(b) Inventory records for hemp products being processed and stored, which include:

1. Date of inventory;
2. Location of stored inventory;
3. Total amount of each hemp product on hand;
4. Total amount of hemp and hemp seed of each variety on hand;
5. Total amount of unusable hemp and hemp seed of each variety on hand; and
6. Name, signature, and title of the employee performing inventory.

(c) Disposal records for all unusable hemp, which include:

1. Date of disposal;
2. Amount of each hemp variety disposed;
3. Method of disposal or destruction;
4. Location of disposal or destruction; and
5. Name, signature, and title of employee responsible for disposal or destruction.

(d) Processing records, which include:

1. List of products produced from hemp; and
2. List of buyers or recipients of hemp products including:

- (i) Name, address, and phone number of each buyer or recipient;
- (ii) Description of each product purchased or otherwise distributed;
- (iii) Quantity of each product purchased or otherwise distributed; and
- (iv) Date of distribution.

(3) Permittees must keep and maintain copies of all records, documents, and information required by this Rule for at least three (3) years and in a manner such that they can be readily provided to the Department upon request.

(4) The Department will maintain all relevant records and information regarding Permittees and facilities at which hemp is processed or handled in Georgia, including a legal description for property on which each processing or handling facility is located, for a period of not less than three (3) calendar years.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.09

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Recordkeeping Requirements" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.10 Hemp Processor Compliance Inspections**

- (1) Processors may subject to compliance inspections.
- (2) The Processor's operational procedures, documentation, recordkeeping, and other practices may be verified during the compliance inspection.
- (3) The Department may assess whether required reports, records, and documentation are being properly maintained and may assess accuracy and completeness.
- (4) If during a compliance inspection the Department determines that the Processor is not in compliance with the Georgia Hemp Farming Act or these Rules, the Department will require a Corrective Action Plan. The Processor's implementation of a Corrective Action Plan will be reviewed by the Department during future compliance inspections.
- (5) Compliance inspections may be unannounced and conducted at any time during regular business hours. The Department will have complete and unrestricted access during business hours to all hemp, hemp products, land, buildings and other structures used for the processing and handling of hemp. The Department will also have complete and unrestricted access to any and all records, documents, and information required to be kept and maintained in accordance with these Rules.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.10

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Hemp Processor Compliance Inspections" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **40-32-3-.11 Violations and Enforcement**

- (1) Violations include, but are not limited to, the following:
  - (a) Processing or handling hemp or hemp products without a Hemp Processor Permit from the Department;

- (b) Processing or handling any cannabis that is not hemp;
  - (c) Processing or handling hemp or hemp products that exceeds the acceptable hemp THC level;
  - (d) Processing hemp that was not lawfully produced under a State or Tribal hemp plan approved by the USDA, under a hemp license issued by USDA, or under [7 U.S.C. 5940](#) through the State or territory of the Indian Tribe, as applicable;
  - (e) Selling, transferring, shipping, transporting, delivering, distributing, or otherwise providing hemp or hemp products that exceeds the acceptable hemp THC level;
  - (f) Processing or handling hemp or hemp products at a facility not approved by the Department as part of the Hemp Processor Permit;
  - (g) Allowing unsupervised public access to hemp processing or handling areas, including storage areas;
  - (h) Denying any Department or law enforcement official access for compliance, sampling, or inspection purposes;
  - (i) Failure to keep and maintain any records, documents, or information required by these Rules;
  - (j) Failure to make any timely report required by these Rules;
  - (k) Failure to comply with any transportation requirement established by these Rules;
  - (l) Failure to comply with any Permittee Restriction;
  - (m) Failure to comply with any Processor Permit Term or Condition; and
  - (n) Failure to comply with, or any violation of, any other provision of the Georgia Hemp Farming Act or these Rules.
- (2) A violation of the Georgia Hemp Farming Act or these Rules will be subject to enforcement in accordance with the Georgia Hemp Farming Act, these Rules, and other applicable state law.
- (3) If the Commissioner determines that a Permittee has violated the Georgia Hemp Farming Act or these Rules with a culpable mental state greater than negligence, the Commissioner will immediately report the Permittee to the United States Attorney General and the Georgia Attorney General.

**Cite as** Ga. Comp. R. & Regs. R. 40-32-3-.11

**AUTHORITY:** O.C.G.A. § [2-23-12](#).

**HISTORY:** Original Rule entitled "Violations and Enforcement" adopted. F. Feb. 10, 2020; eff. Mar. 1, 2020.

# **Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH**

## **Chapter 111-8. HEALTHCARE FACILITY REGULATION**

### **Subject 111-8-37. RULE AND REGULATIONS FOR HOSPICES**

#### **111-8-37-.07 Governing Body**

- (1) The hospice must have an established and functioning governing body that is responsible for the conduct of the hospice and that provides for effective hospice governance, management, and budget planning.
- (2) The governing body must appoint an administrator and delegate to the administrator the authority to operate the hospice in accordance with these rules and management policies established and approved by the governing body.
- (3) The governing body must appoint a medical director and delegate to the medical director the authority to establish and approve, in accordance with current accepted standards of care, all patient care policies related to medical care.
- (4) The governing body must ensure that no member of the governing body, administration, staff associated or affiliated with the hospice, or family member of staff causes, encourages or coerces any patient or family member of a patient to:
  - (a) name any person associated or affiliated with the hospice as a beneficiary under a will, trust, or life insurance policy;
  - (b) take out or otherwise secures a life insurance policy on any patient; or
  - (c) give or loan anything of value to a member of the governing body, administration, staff associated or affiliated with the hospice or family member of staff.
- (5) The governing body must be responsible for determining, implementing, and monitoring the overall operation of the hospice, including the quality of care and services, management, and budget planning. The governing body must:
  - (a) Be responsible for ensuring the hospice functions within the limits of its current license granted by the Department;
  - (b) Ensure that the hospice provides coordinated care that includes at a minimum medical, nursing, social, spiritual, volunteer, and bereavement services that meet the needs of the patients;
  - (c) Ensure that the hospice is staffed and equipped adequately to provide the services it offers to patients, whether the services are provided directly by the hospice or under contract;
  - (d) Develop and make available to patients and their families, a description of services offered by the hospice, including patient eligibility for the various services and whether the hospice provides palliative care to patients who have not been determined to be terminally ill but have been diagnosed with an advanced and progressive disease;
  - (e) Ensure the development and implementation of effective policies and procedures that address the management, operation, and evaluation of the hospice, including all patient care services and those services provided by independent contractors;

(f) Ensure there is an individual authorized in writing to act for the administrator during any period the administrator is absent;

(g) Appoint an individual to assume overall responsibility for a quality assurance, utilization, and peer review program for monitoring and evaluating the quality and level of patient care in the hospice on an ongoing basis;

(h) Ensure that hospice advertisements are factual and do not contain any element that might be considered coercive or misleading;

(i) Ensure that hospice care to patients who have been determined to be terminally ill is provided regardless of the patient or the family unit's ability to pay; and

(j) Ensure that there are policies and procedures in place that specify the manner in which transitions across care sites and providers (e.g. hospital to home hospice) will be handled to ensure that communications are effective to address continuity of care issues for the patient.

(6) The governing body shall comply with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12, as applicable.

**AUTHORITY:** O.C.G.A. §§ [31-7-170](#) et seq., [31-7-350](#) et seq.

**HISTORY:** Original Rule entitled "Governing Body" adopted. F. May 26, 2015; eff. June 15, 2015.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-37-.08 Administrator**

(1) Each hospice must have a qualified administrator, designated by the governing body, who must be responsible for the ongoing and day-to-day operation of the hospice.

(2) The hospice administrator must be either a Georgia-licensed health care professional, who has at least one year of supervisory or management experience in a hospice setting or an individual with education, training and experience in health services administration and at least two years of supervisory or management experience in a hospice setting. The term, licensed health care professional, includes the following who hold Georgia licenses: physicians, nurse practitioners, physicians' assistants, registered professional nurses, clinical social workers, physical therapists and psychologists, but does not include practical nurses.

(3) The hospice administrator must ensure that the hospice:

(a) Implements policies and procedures for the provision of hospice care and palliative care to persons with advanced and progressive diseases, if it offers such services, which have been developed with interdisciplinary participation from the hospice care team;

(b) Employs qualified staff, including physicians, practitioners, nurses, social workers, clergy, volunteers, or other persons providing services at the hospice;

(c) Has implemented policies and procedures related to the management, operation, and evaluation of the overall performance of the hospice;

(d) Has a qualified director of nursing services along with sufficient qualified staff to meet the needs of patients admitted for hospice care and palliative care, if offered to persons with advanced and progressive diseases but who have not been determined to be terminally ill, and as outlined in the patients' plans of care;

(e) Provides an orientation, training, and supervision program for every employee and volunteer that addresses hospice care and palliative care for persons with advanced and progressive diseases, when offered, and the performance of the specific job to which the employee or volunteer is assigned;

- (f) Ensures that the staff members complete their annual training and education program; and
  - (g) Ensures that there are effective mechanisms to facilitate communication among the hospice staff, hospice care team, and patients, their family units, and their legal guardians, if any.
- (4) The hospice administrator shall comply with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12, as applicable.

**AUTHORITY:** O.C.G.A. §§ [31-7-170](#) et seq., 31-7-350 et seq.

**HISTORY:** Original Rule entitled "Administrator" adopted. F. May 26, 2015; eff. June 15, 2015.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-37-.11 Disaster Preparedness**

- (1) Every hospice must have a current disaster preparedness plan that addresses potential situations where services to patients may be disrupted and outlines appropriate courses of action in the event a local or widespread disaster occurs including communications with patients and their families and emergency management agencies.
- (2) The disaster preparedness plan must include at a minimum plan for the following emergency situations:
- (a) Local and widespread severe weather emergencies or natural disasters, such as floods, ice or snowstorms, tornados, hurricanes, and earthquakes;
  - (b) Interruption of service of utilities, including water, gas, or electricity, either within the facility or patients' homes or within a local or widespread area; and
  - (c) Coordination of continued care in the event of an emergency evacuation of the area.
- (3) If the hospice offers residential and/or inpatient services, in addition to the procedures specified in paragraph (2) of this rule, the plan must also include:
- (a) Fire safety and evacuation procedures and procedures for the provision of emergency power, heat, air conditioning, food, and water; and
  - (b) Plans for the emergency transport or relocation of all or a portion of the hospice patients, should it be necessary, in vehicles appropriate to the patients' conditions when possible, including written agreements with any facilities which have agreed to receive the hospice's patients in such situations, and notification of the patients' representatives.
- (4) The hospice must have plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.
- (5) The plan must be reviewed and revised annually, as appropriate, including any related written agreements.
- (6) Disaster preparedness plans for hospice care facilities must be rehearsed at least annually. Rehearsals must be documented to include staff and patient participants, a summary of any problems identified, and the effectiveness of the rehearsal. In the event an actual disaster occurs in any given year, the hospice may substitute the actual disaster's response in place of that year's rehearsal.
- (7) Hospices must include emergency management agencies in the development and maintenance of their disaster preparedness plans and also provide copies of such plans to those agencies as requested.

(8) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared that a state of emergency or disaster exists as a result of a public health emergency.

**AUTHORITY:** O.C.G.A. §§ [31-7-170](#) et seq., 50-13-4.

**HISTORY:** Original Rule entitled "Disaster Preparedness" adopted. F. May 26, 2015; eff. June 15, 2015.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-37-.13 Human Resources**

(1) All persons providing services for a hospice must be qualified by education, training, and experience to carry out all duties and responsibilities assigned to them.

(2) All persons providing services for a hospice must receive an orientation to the hospice to include, but not be limited to:

(a) Hospice concepts and philosophy;

(b) Patient rights including abuse reporting requirements; and

(c) Hospice policies and procedures, including, but not limited to, disaster preparedness, fire safety and emergency evacuations, and reporting abuse and neglect.

(3) Where a patient does not have a do-not-resuscitate order, the hospice must ensure that all persons providing hands-on care directly to that patient on behalf of the licensed hospice have current certification in basic cardiac life support (BCLS) or cardiopulmonary resuscitation.

(4) The hospice must have an effective annual training and education program for all staff and volunteers who provide hands-on care to patients that addresses at a minimum:

(a) Emerging trends in infection control;

(b) Recognizing abuse and neglect and reporting requirements;

(c) Patient rights; and

(d) Palliative care.

(5) The administrator and each staff member and volunteer who has direct contact with patients or their family units must receive an initial and annual health screening evaluation, performed by a licensed health care professional in accordance with accepted standards of practice, sufficient in scope to ensure that the staff and volunteers screened are free of communicable and health diseases that pose potential risks to patients, their family units, and other staff and volunteers.

(6) Human resource files must be maintained for the following individuals delivering any services associated with the written plan of care: each staff member, independent contractor, and volunteer. The files must contain the person's application, employment history, emergency contact information, evidence of qualifications, job description, evidence of initial and annual health screening, yearly skills competency assessments, evidence of verified licensure or certification, and criminal record check as appropriate, and evidence of orientation, education, and training. These files must be available for inspection by the appropriate enforcement authorities on the premises.

(7) Where the hospice contracts with a staffing agency to provide any services specified in a plan of care, the written contract must require the contracting agency to verify licensing credentials, where applicable, of contract workers to

ensure that such workers meet the same qualifications and licensure requirements as specified for hospice employees providing such services directly. The hospice must retain a copy of the contract.

(8) The hospice must comply with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12, with respect to direct access employees and maintain documentation of a satisfactory fingerprint criminal record check determination in the individual's personnel file.

**AUTHORITY:** O.C.G.A. §§ [31-7-170](#) et seq., [31-7-350](#) et seq.

**HISTORY:** Original Rule entitled "Human Resources" adopted. F. May 26, 2015; eff. June 15, 2015.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-37-.21 Pharmaceutical Services**

(1) The hospice must provide for the procurement, storage, administration, and destruction of drugs and biologicals utilized for hospice care in accordance with accepted professional principles and in compliance with all applicable state and federal laws.

(2) The hospice must:

(a) Ensure medication and pharmacy procedures are approved by a licensed pharmacist who is either employed directly or has a formal arrangement with the hospice;

(b) Ensure the availability of a licensed pharmacist on a 24-hour per day basis to advise the hospice staff regarding medication issues and to dispense medications;

(c) Ensure that any emergency drug kit placed in the hospice is in accordance with all applicable laws and rules and regulations;

(d) Ensure that drugs and biologicals are labeled in accordance with current accepted standards of practice;

(e) Ensure effective procedures for control and accountability of all drugs and biologicals throughout the hospice, including records of receipt, disposition, destruction, and reconciliation of all controlled substances and dangerous drugs; and

(f) Ensure that only licensed nurses or physicians, acting within the scope of their licenses, administer medications on behalf of the hospice, except for liquid morphine administered in accordance with O.C.G.A. § [31-7-12.2\(g\)\(7\)\(G\)](#).

(3) In the event of special circumstances under which the hospice is unavailable to administer liquid morphine to a hospice patient residing in an assisted living community, the hospice may train a certified medication aide at the community to administer the medication, subject to the following requirements:

(a) The patient is under a physician's written order that contains specific instructions for indication, dosage, frequency and route of administration;

(b) The initial dose is administered by a licensed hospice health care professional;

(c) The hospice provides adequate training to ensure that the medication aide who will be administering the liquid morphine can do so safely and properly;

(d) The morphine administration training is repeated at least on an annual basis to ensure continuing competency; and

(e) The hospice maintains documentation of compliance with these requirements.

**AUTHORITY:** O.C.G.A. §§ [31-7-170](#) et seq., [31-7-12.2\(g\)\(7\)\(G\)](#).

**HISTORY:** Original Rule entitled "Pharmaceutical Services" adopted. F. May 26, 2015; eff. June 15, 2015.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

# **Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH**

## **Chapter 111-8. HEALTHCARE FACILITY REGULATION**

### **Subject 111-8-62. PERSONAL CARE HOMES**

#### **111-8-62-.03 Definitions**

In these rules, unless the context otherwise requires, the words, phrases and symbols shall mean the following:

(a) "Abuse" means any intentional or grossly negligent act or series of acts or intentional or grossly negligent omission to act which causes injury to a resident, including but not limited to, assault or battery, failure to provide treatment or care, or sexual harassment of the resident.

(b) "Activities of daily living" means bathing, shaving, brushing teeth, combing hair, toileting, dressing, eating, laundering, cleaning private living space, managing money, writing letters, shopping, using public transportation, making telephone calls, grooming, obtaining appointments, engaging in leisure and recreational activities, or other similar activities.

(c) "Administrator" means the manager designated by the governing body as responsible for the day-to-day management, administration and supervision of the personal care home, who may also serve as the on-site manager and responsible staff person except during periods of his or her own absence.

(d) "Ambulatory Resident" means a resident who has the ability to move from place to place by walking, either unaided or aided by prosthesis, brace, cane, crutches, walker or hand rails, or by propelling a wheelchair or scooter; who can respond to an emergency condition, whether caused by fire or otherwise, and escape with minimal human assistance such as guiding a resident to an exit, using the normal means of egress.

(e) "Applicant" means any of the following:

1. When the personal care home is owned by a sole proprietorship, the individual proprietor shall be the applicant for the license, complete the statement of responsibility and serve as the licensee.
2. When the personal care home is owned by a partnership, the general partners shall be the applicant for the license, complete the statement of responsibility and serve as the licensee.
3. When the personal care home is owned by an association or limited liability company (LLC), the governing body of the association or LLC shall authorize the application for the license and complete the statement of responsibility and the association shall serve as the licensee.
4. When the personal care home is owned by a corporation, the governing body of the corporation shall authorize the application for the license and complete the statement of responsibility and the corporation shall serve as the licensee.

(f) "Assisted living care" means the specialized care and services provided by an assisted living community which includes the provision of personal services, the administration of medications by a certified medication aide and the provision of assisted self-preservation.

(g) "Chemical Restraint" means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

- (h) "Department" means the Georgia Department of Community Health operating through the Division of Healthcare Facility Regulation.
- (i) "Disabled individual" means an individual that has a physical or mental impairment that substantially limits one or more major life activities and who meets the criteria for a disability under state or federal law.
- (j) "Employee" means any person, other than a director, utilized by a personal care home to provide personal services to any resident on behalf of the personal care home or to perform at any facilities of the personal care home any duties which involve personal contact between that person and any paying resident of the personal care home.
- (k) "Exploitation" means an unjust or improper use of another person or the person's property through undue influence, coercion, harassment, duress, deception, false representation, false pretense, or other similar means for one's own personal advantage.
- (l) "Governing Body" means the person or group of persons as defined in Georgia law who maintain and control the home and who are legally responsible for the operation of the home.
- (m) "Health services" means the specialized assistance that may be provided by or at the direction of either licensed healthcare professionals, such as doctors, nurses, physical therapists or through licensed healthcare programs, such as home health agencies, hospices and private home care providers to address health needs that the home is not authorized by law or regulations to provide.
- (n) "Injury" as used in the definition of abuse means a wrong or harm caused by an individual to a resident which is manifested by a physical or behavioral reaction or change in the appearance or actions of the resident, such as, but not limited to, reddened or bruised skin not related to routine care, crying, startling or cowering reaction by the resident and malnutrition or pressure ulcers, such as skin breakdowns, for which the home has not provided proper care.
- (o) "Legal Surrogate" means a duly appointed person who is authorized to act, within the scope of the authority granted under the legal surrogate's appointment, on behalf of a resident who is adjudicated or certified incapacitated. The legal surrogate may act on a resident's behalf where a resident has not been adjudicated as incapacitated provided that the action is consistent with the resident's wishes and intent and is within the scope of the authority granted. Where such authority is exercised pursuant to a Power of Attorney executed by a resident, the facility must maintain a copy of this document in the resident's files. The resident's duly appointed legal surrogate(s) shall have the authority to act on the resident's behalf as established by written applicable federal and state of Georgia law, and shall be entitled to receive information relevant to the exercise of his or her authority. No member of the governing body, administration, or staff of the personal care home or affiliated personal care homes or their family members may serve as the legal surrogate for a resident.
- (p) "Medical services" means services which may be provided by a person licensed pursuant to Article II of Chapter 34 of Title 43 of the Official Code of Georgia Annotated. or appropriately licensed and supervised nurse practitioners and physicians assistants.
- (q) "Memory care services" means the additional watchful oversight systems, program, activities and devices that are required for residents who have cognitive deficits which may impact memory, language, thinking, reasoning, or impulse control, and which place the residents at risk of eloping, i.e., engaging in unsafe wandering activities outside the home.
- (r) "Memory care unit" means the specialized unit or home that either holds itself out as providing memory care services or provides personal services in secured surroundings.
- (s) "Non-Family Adult" means a resident 18 years of age or older who is not related by blood within the third degree of consanguinity or by marriage to the person responsible for the management of the personal care home or to a member of the governing body.

(t) "Nursing services" means those services which may be rendered by a person licensed pursuant to Articles I and 2 of Chapter 26 of Title 43 of the Official Code of Georgia Annotated.

(u) "On-site manager" means the administrator or person designated by the administrator as responsible for carrying on the day-to-day management, supervision, and operation of the personal care home, who may also serve as the responsible staff person except during periods of his or her own absence.

(v) "Owner" means any individual or any person affiliated with a corporation, partnership, or association with 10 percent or greater ownership interest in the facility providing care to persons under the license of the facility in this state and who:

1. purports to or exercises authority of the owner in a facility;
2. applies to operate or operates a facility;
3. maintains an office on the premises of a facility;
4. resides at a facility;
5. has direct access to persons receiving care at a facility;
6. provides direct personal supervision of facility personnel by being immediately available to provide assistance and direction during the time such facility services are being provided; or
7. enters into a contract to acquire ownership of a facility.

(w) "Permit" or "Regular Permit" means the authorization granted by the Department to the governing body to operate a Personal Care Home.

(x) "Personal Care Home", "home" or "facility" means any dwelling, whether operated for profit or not, which undertakes through its ownership or management to provide or arrange for the provision of housing, food service, and one or more personal services for two or more adults who are not related to the owner or administrator by blood or marriage.

(y) "Personal Services" includes, but is not limited to, individual assistance with or supervision of self-administered medication, assistance with ambulation and transfer, and essential activities of daily living such as eating, bathing, grooming, dressing, and toileting.

(z) "Proxy caregiver" means an unlicensed person or a licensed health care facility that has been selected by a disabled individual or a person legally authorized to act on behalf of such individual to serve as such individual's proxy caregiver and meets the requirements contained in the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100.

(aa) "Physical Restraints" are any manual or physical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom or normal access to one's body. Physical restraints include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, and wheelchair safety bars. Also included as restraints are practices employed by the home which function as a restraint, such as tucking in a sheet so tightly that a bedbound resident cannot move, bedrails, or chairs that prevent rising, or placing a wheelchair-bound resident so close to a wall that the wall prevents the resident from rising. Wrist bands or devices on clothing that trigger electronic alarms to warn staff that a resident is leaving a room do not, in and of themselves, restrict freedom of movement and should not be considered as restraints.

(bb) "Plan of Correction" means the written plan prepared in response to cited rule violations which identify by date certain the specific actions that will be taken by the personal care home to come into compliance with applicable rules.

(cc) "Representative" means a person who voluntarily, with the resident's written authorization, may act upon resident's direction with regard to matters concerning the health and welfare of the resident, including being able to access personal records contained in the resident's file and receive information and notices pertaining to the resident's overall care and condition. This written authorization may take the form of an advance directive.

(dd) "Resident" means any non-family adult receiving or requiring personal assistance and residing in a personal care home.

(ee) "Responsible Staff Person" means the employee designated by the administrator or on-site manager as responsible for supervising the operation of the home during periods of temporary absence of the administrator or on-site manager.

(ff) "Self-administration of medications" or "self-administered medications" means those prescription or over-the-counter drugs that the resident personally chooses to ingest or apply where the resident has been assessed and determined to have the cognitive skills necessary to articulate the need for the medications and generally knows the times the medications are to be taken, and physical characteristics of medications to be taken.

(gg) "Self-preservation" means the ability to respond to an emergency condition, whether caused by fire or otherwise, and escape the emergency without physical, hands-on assistance from staff. The resident may move from place to place by walking, either unaided or aided by prosthesis, brace, cane, crutches, walker or hand rails, or by propelling a wheelchair or scooter.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-2-8](#), [31-2-9](#), [31-7-2.1](#), [31-7-3](#), [31-7-12](#), [31-7-12.2](#), [31-7-12.3](#), [31-8-80](#) et seq.

**HISTORY:** Original Rule entitled "Definitions" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.

**Amended:** F. Dec. 19, 2012; eff. Jan. 8, 2013.

**Amended:** F. Apr. 16, 2018; eff. May 6, 2018.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-62-.09 Workforce Qualifications and Training**

(1) Age Requirements. The on-site manager and all other direct-care supervisory staff working in a personal care home must be at least 21 years of age. Non-supervisory staff providing hands-on care to the residents must be at least 18 years of age.

(2) The administrator or on-site manager must be responsible for ensuring that any person working in the home as an employee, under contract or otherwise, receives work-related training within the first sixty days of employment. Such training must include, at a minimum, the following:

(a) Evidence of current certification in emergency first aid except where the staff person is a currently licensed health care professional;

(b) Evidence of current certification in cardiopulmonary resuscitation where the training course required return demonstration of competency;

(c) Emergency evacuation procedures;

(d) Medical and social needs and characteristics of the resident population;

(e) Residents' rights;

(f) Identification of conduct constituting abuse, neglect or exploitation of a resident and reporting requirements to include the employee's receipt of a copy of the Long-Term Care Facility Resident Abuse Reporting Act as outlined in O.C.G.A. § [31-8-81](#) *et seq.*; and

(g) General infection control principles including the importance of hand hygiene in all settings and attendance policies when ill.

(3) At least one staff person having completed the minimum training requirements of Rule [111-8-62-.09\(2\)\(a\) through \(g\)](#) above must be present in the home at all times resident(s) are present in the home. Where the home provides a secure unit, the unit itself must have at least one person present in the unit who has completed all the required training.

(4) All persons, including the administrator or on-site manager, who offer direct care to the residents, must satisfactorily complete continuing education each year, in courses, relevant to their job duties, including, but not limited to, appropriate medication assistance, working with the elderly, working with residents with Alzheimer's or other cognitive impairments, working with the mentally retarded, mentally ill and developmentally disabled, social and recreational activities, legal issues, physical maintenance and fire safety, housekeeping, or other topics as needed or as determined by the Department.

(5) All directors and employees involved with the provision of personal services to the residents must have at least sixteen (16) hours of training per year.

(6) The administrator, on-site manager, and each employee must have received a tuberculosis screening and a physical examination by a licensed physician, nurse practitioner or physician assistant within twelve months prior to their employment with the home which examination was sufficiently comprehensive to assure that the employee is free of diseases communicable within the scope of employment and physically qualified to work. Follow-up examinations must be conducted by a licensed physician, nurse practitioner or physician assistant of each administrator or staff person to determine readiness to return to work following a significant illness or injury. Copies of information regarding staff member health must be kept in the staff person's file accessible at the licensed home or within one hour of the request.

(7) **Criminal History Background Checks for Owners Required.** Prior to the issuance of any new license, the owner of the business or agency applying for the license must comply with the requirements of the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(8) **Criminal History Background Checks for Directors, Administrators and Onsite Managers Required.** The home must obtain a satisfactory fingerprint records check determination for the person being considered for employment as a director, administrator or onsite manager. The records check determination must be done in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(9) **Criminal History Background Checks for Direct Access Employees Required.** Prior to serving as a direct access employee, the home must obtain a satisfactory fingerprint records check determination for the person to be hired in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(10) The administrator or on-site manager must obtain and verify a five year employment history when possible for each employee and maintain documentation in the employee's file. If the potential employee has no prior employment history, then the home must retain documentation of a satisfactory personal reference check.

(11) Personnel file(s) for each employee must be maintained either in the home or available for inspection by departmental staff within one hour of request or prior to the end of the on-site survey and for three years following the employee's departure or discharge. These files must include all of the following:

(a) Evidence of a satisfactory fingerprint record check determination, if applicable.

(b) Report of a physical examination completed by a licensed physician, nurse practitioner or physician assistant.

(c) Evidence of trainings, skills competency determinations and recertifications as required by these rules and, if applicable, the Rules for Proxy Caregivers, Chapter 111-8-100.

(d) Employment history, if previously employed, including places of work, employers and telephone contacts with previous employers.

(e) Supporting documentation reflecting that the employee has the basic qualifications as represented, e.g. personal references, documentation of good standing by nursing board, no findings of abuse, neglect or exploitation entered against the individual in the nurse aide registry, satisfactory report of motor vehicle driving record where the employee may be transporting residents.

(f) Written evidence of satisfactory initial and annual work performance reviews, which can take the form of skills competency checklists, for unlicensed staff providing hands-on personal care. Where the unlicensed staff performs specialized tasks, such as health maintenance activities, such performance reviews must include the satisfactory completion of skills competency checklists as specified in applicable rules. Such reviews must be conducted by staff or contractors qualified by education, training and experience to assess that the assigned duties are being performed in accordance with applicable rules and accepted health and safety standards.

(12) Where the home permits a resident to hire his or her own companion-sitter, proxy caregiver to perform health maintenance activities or aide of any sort, the home must require assurance that the companion-sitter, proxy caregiver or aide so hired is familiar with emergency evacuation routes and has documentation reflecting compliance with the provisions of the Rules for Proxy Caregivers, Chapter 111-8-100, as applicable.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-2-9](#), [31-7-2.1](#), [31-7-12](#), [31-7-350](#).

**HISTORY:** Original Rule entitled "Administration" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.

**Amended:** New Title "Workforce Qualifications and Training". F. Dec. 19, 2012; eff. Jan. 8, 2013.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-62-.11 Home Accountability and Inspections**

(1) The home and its records must be available for review and examination by properly identified representatives of the Department. Inspections may be conducted both on an announced and unannounced basis. Unannounced inspections shall be conducted as needed.

(2) Where the Department identifies rule violations, the home will receive a written report of inspection. Within 10 days of receipt of the written report of inspection, the home must develop a written plan for correcting any rule violations identified. The plan of correction must identify the specific actions the home will take promptly to come into compliance with each rule for which a deficient practice was identified and file the plan with the Department as directed.

(3) If the home disagrees with the facts and conclusions stated in the inspection report, the home may include with its plan of correction a written statement explaining its disagreement and any evidence supporting the disagreement to the Department. Where the Department concurs with the written statement of disagreement, the Department will issue a revised inspection report to the home.

(4) A copy of the most recent inspection report and plan of correction must be displayed in the home in a location that is routinely used by the home to communicate information to residents and visitors. Additionally, if the home maintains a website, it shall post a web link in a prominent location on the main page of the website that provides access to copies of all inspection reports and plans of correction from the previous 18 months. When the Department develops a web site for receiving plans of correction electronically and notifies the home of the appropriate internet address, the home also must file its plan of correction electronically on the Department's web site within 10 days of receipt of the report of inspection.

(5) The home must assess the effectiveness of its plan of correction in correcting the deficient practice and modify the plan of correction as necessary to ensure compliance with the rules.

(6) The home must complete and maintain an accurate and current licensed residential care profile on file with the Department when the Department makes available a system for the submission and collection of such information electronically.

(7) The home must provide services that are consistent with the information reported on its licensed residential care profile, its license and these rules.

(8) A personal care home which is not licensed as an assisted living community must not use the term "assisted living" in its name or marketing materials.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-7-1](#), [31-7-3](#), [31-7-2.1](#), [31-7-12](#), [31-7-12.2](#), [31-7-12.3](#).

**HISTORY:** Original Rule entitled "Staffing" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.

**Amended:** New Title "Home Accountability and Inspections". F. Dec. 19, 2012; eff. Jan. 8, 2013.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

# **Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH**

## **Chapter 111-8. HEALTHCARE FACILITY REGULATION**

### **Subject 111-8-63. RULES AND REGULATIONS FOR ASSISTED LIVING COMMUNITIES**

#### **111-8-63-.03 Definitions**

In these rules, unless the context otherwise requires, the words, phrases and symbols set forth herein shall mean the following:

(a) "Abuse" means any intentional or grossly negligent act or series of acts or intentional or grossly negligent omission to act which causes injury to a resident, including but not limited to, assault or battery, failure to provide treatment or care, or sexual harassment of the resident.

(b) "Activities of daily living" means bathing, shaving, brushing teeth, combing hair, toileting, dressing, eating, walking, transferring from place to place, laundering, cleaning room, managing money, writing letters, shopping, using public transportation, making telephone calls, grooming, obtaining appointments, engaging in leisure and recreational activities, or other similar activities.

(c) "Administrator" means the manager designated by the Governing Body as responsible for the day-to-day management, administration and supervision of the assisted living community, who may also serve as the on-site manager and responsible staff person except during periods of his or her own absence.

(d) "Applicant" means an individual or entity that submits an application for licensure pursuant to these rules as described below:

1. When the assisted living community is owned by a sole proprietorship, the individual proprietor must be the applicant for the license, complete the statement of responsibility and serve as the licensee;
2. When the assisted living community is owned by a partnership, the general partners must be the applicant for the license, complete the statement of responsibility and serve as the licensee;
3. When the assisted living community is owned by an association, limited liability company (LLC) the governing body of the association or LLC must authorize the application for the license, complete the statement of responsibility and serve as the licensee; and
4. When the assisted living community is owned by a corporation, the governing body of the corporation must authorize the application for the license, complete the statement of responsibility and serve as the licensee.

(e) "Assistive device" means a device that may restrain movement which has been determined to be required by a licensed physician, nurse practitioner or physician's assistant working under a protocol or job description respectively and is applied for protection from injury or to support or correct the body alignment of the person, for the treatment of a person's physical condition, and may only be used as a treatment intervention where a specific written plan of care has been developed and the resident consents to such use.

(f) "Assisted living care" means the specialized care and services provided by an assisted living community which includes the provision of personal services, the administration of medications by a certified medication aide and the provision of assisted self-preservation.

(g) "Assisted living community" or "community" means a personal care home serving 25 residents or more that is licensed by the department to provide assisted living care.

(h) "Assisted self-preservation" means the capacity of a resident to be evacuated from an assisted living community to a designated point of safety and within an established period of time as determined by the Office of Fire Safety Commissioner. Assisted self-preservation is a function of all of the following:

1. the condition of the individual,
2. the assistance that is available to be provided to the individual by the staff of the assisted living community; and
3. the construction of the building in which the assisted living community is housed, including whether such building meets the state fire safety requirements applicable to an existing health care occupancy.

(i) "Chemical Restraint" means a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

(j) "Department" means the Department of Community Health of the State of Georgia operating through the Division of Healthcare Facility Regulation.

(k) "Director" means the chief administrator, executive officer or manager.

(l) "Disabled individual" means an individual that has a physical or mental impairment that substantially limits one or more major life activities and who meets the criteria for a disability under state or federal law.

(m) "Employee" means any person, other than a director, utilized by an assisted living community to provide personal services to any resident on behalf of the assisted living community or to perform at any facilities of the assisted living community any duties which involve personal contact between that person and any paying resident of the assisted living community.

(n) "Exploitation" means an unjust or improper use of another person or the person's property through undue influence, coercion, harassment, duress, deception, false representation, false pretense, or other similar means for one's own personal advantage.

(o) "Governing Body" means the owner, the board of trustees or directors, the partnership, the corporation, the association, the sole proprietorship or the person or group of persons who maintains and controls the assisted living community and who is legally responsible for the operation of the community.

(p) "Health maintenance activities" means those limited activities that, but for a disability, a person could reasonably be expected to do for himself or herself. Such activities are typically taught by a registered professional nurse, but may be taught by an attending physician, advanced practice registered nurse, physician assistant, or directly to a patient and are part of ongoing care. Health maintenance activities are those activities that do not include complex care such as administration of intravenous medications, central line maintenance, and complex wound care; do not require complex observations or critical decisions; can be safely performed and have reasonably precise, unchanging directions; and have outcomes or results that are reasonably predictable. Health maintenance activities conducted pursuant to this paragraph shall not be considered the practice of nursing.

(q) "Health services" means the specialized assistance that may be provided by or at the direction of either licensed healthcare professionals, such as doctors, nurses, physical therapists or through licensed healthcare programs, such as home health agencies, hospices and private home care providers to address health needs that the assisted living community is not staffed to provide or is not authorized by law or regulations to provide.

(r) "Injury" as used in the definition of "abuse" means a wrong or harm caused by an individual to a resident which is manifested by a physical or behavioral reaction or change in the appearance or actions of the resident, such as, but not limited to, reddened or bruised skin not related to routine care, crying, startling or cowering reaction by the resident and malnutrition or pressure ulcers for which the facility has not provided proper care.

(s) "Legal Surrogate" means a duly appointed person who is authorized to act, within the scope of the authority granted under the legal surrogate's appointment, on behalf of a resident who is adjudicated incapacitated.

(t) "Medical services" means services which may be provided by a person licensed pursuant to Article II of Chapter 34 of Title 43 of the Official Code of Georgia Annotated.

(u) "Memory care services" means the additional watchful oversight systems and devices that are required for residents who have cognitive deficits which may impact memory, language, thinking, reasoning, or impulse control, and which place the residents at risk of eloping, i.e. engaging in unsafe wandering activities outside the assisted living community.

(v) "Memory care unit" means the assisted living community or specialized unit, thereof, that either holds itself out as providing additional or specialized care to persons with diagnoses of probable Alzheimer's Disease or other dementia who may be at risk of engaging in unsafe wandering activities outside the unit or assisted living community (eloping) or charges rates in excess of those charged other residents because of cognitive deficits which may place the residents at risk of eloping.

(w) "Non-Family Adult" means a resident 18 years of age or older who is not related by blood within the third degree of consanguinity or by marriage to the person responsible for the management of the assisted living community or to a member of the governing body.

(x) "Nursing services" means those services which may be rendered by a person licensed pursuant to Articles I and 2 of Chapter 26 of Title 43 of the Official Code of Georgia Annotated.

(y) "On-site manager" means the administrator or person designated by the administrator as responsible for carrying out the day-to-day management, supervision, and operation of the assisted living community, who may also serve as responsible staff person except during periods of his or her own absence.

(z) "Owner" means any individual or any person affiliated with a corporation, partnership, or association with 10 percent or greater ownership interest in the business or agency licensed as an assisted living community and who:

1. purports to or exercises authority of an owner in the business or agency;
2. applies to operate or operates the business or agency;
3. maintains an office on the premises of the assisted living community;
4. resides at the assisted living community;
5. has direct access to persons receiving care at the assisted living community;
6. provides direct personal supervision of assisted living community personnel by being immediately available to provide assistance and direction during the time such assisted living community services are being provided; or
7. enters into a contract to acquire ownership of such a business or agency.

(aa) "Permit" or "license" means the authorization granted by the Department to the governing body to operate an assisted living community.

(bb) "Personal care home" means any dwelling, whether operated for profit or not, which undertakes through its ownership or management to provide or arrange for the provision of housing, food service, and one or more personal services for two or more adults who are not related to the owner or administrator by blood or marriage.

(cc) "Personal Services" includes, but is not limited to, individual assistance with or supervision of self-administered medication, assistance, essential activities of daily living such as eating, bathing, grooming, dressing, toileting, ambulation and transfer.

(dd) "Proxy caregiver" means an unlicensed person or a licensed health care facility that has been selected by a disabled individual or a person legally authorized to act on behalf of such individual to serve as such individual's proxy caregiver and meets the requirements contained in the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100.

(ee) "Physical Restraints" are any manual or physical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom or normal access to one's body. Physical restraints include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, and wheelchair safety bars. Also included as restraints are assisted living community practices which function as a restraint, such as tucking in a sheet so tightly that a bedbound resident cannot move, bedrails, or chairs that prevent rising, or placing a wheelchair-bound resident so close to a wall that the wall prevents the resident from rising. Wrist bands or devices on clothing that trigger electronic alarms to warn staff that a resident is leaving a room do not, in and of themselves, restrict freedom of movement and should not be considered as restraints.

(ff) "Plan of Correction" means the written plan prepared in response to cited rule violations that identifies by date certain the specific actions that will be taken by the assisted living community to come into compliance with these rules.

(gg) "Representative" means a person who voluntarily, with the resident's written authorization, acts upon resident's direction with regard to matters concerning the health and welfare of the resident, including being able to access personal and medical records contained in the resident's file and receive information and notices pertaining to the resident's overall care and condition. This written authorization may take the form of an advance directive.

(hh) "Resident" means any non-family adult who receives or requires assisted living care and resides in the assisted living community.

(ii) "Responsible Staff Person" means the employee designated by the administrator or on-site manager as responsible for supervising the operation of the assisted living community during periods of temporary absence of the administrator or on-site manager.

(jj) "Self-administration of medications" or "self-administered medications" means those prescription or over-the-counter drugs that the resident personally chooses to ingest or apply where the resident has been assessed and determined to have the cognitive skills necessary to articulate the need for the medication and generally knows the times, and physical characteristics of medications to be taken.

(kk) "Self-preservation" means the ability to respond to an emergency condition, whether caused by fire or otherwise, and escape the emergency without physical, hands-on assistance from staff. The resident may move from place to place by walking, either unaided or aided by prosthesis, brace, cane, crutches, walker or hand rails, or by propelling a wheelchair.

(ll) "Staff" means any person who performs duties in the assisted living community on behalf of the assisted living community.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-2-8](#), [31-2-9](#), [31-7-1](#), [43-26-12](#).

**HISTORY:** Original Rule entitled "Definitions" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.

**Amended:** F. Dec. 19, 2012; eff. Jan. 8, 2013.

**Amended:** F. Apr. 16, 2018; eff. May 6, 2018.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

## **111-8-63-.09 Workforce Qualifications, Training and Staffing**

(1) **The on-site manager and responsible staff persons must be at least 21 years of age and responsible for supervising the provision of care by all other staff.** No staff person under the age of 18 is permitted to work in the assisted living community unless there is direct line-of-sight supervision being provided by the administrator, on-site manager or a responsible staff person or the staff member is at least 17 years of age and has successfully completed a vocational technical training track as a nursing assistant through a Georgia high school.

(2) **Initial Training for All Staff.** The administrator or on-site manager must ensure that any person working in the assisted living community as staff, receives training within the first 60 days of employment on the following:

(a) residents' rights and identification of conduct constituting abuse, neglect or exploitation of a resident and reporting requirements to include the employee's receipt of a copy of the Long-Term Care Facility Resident Abuse Reporting Act as outlined in O.C.G.A. § [31-8-81](#) *et seq.*;

(b) general infection control principles including importance of hand hygiene in all settings and attendance policies when ill;

(c) training necessary to carry out assigned job duties; and

(d) emergency preparedness.

(3) **Initial Training for Staff Providing Hands-On Personal Services.** In addition to the initial training required of all staff in paragraph (2) above, the administrator must ensure that staff hired to provide hands-on personal services to residents receive training within the first 60 days of employment which includes the following:

(a) current certification in emergency first aid except where the staff person is a currently licensed health care professional;

(b) current certification in cardiopulmonary resuscitation where the training course required return demonstration of competency;

(c) medical and social needs and characteristics of the resident population, including special needs of residents with dementia;

(d) residents' rights and the provision of care to residents that is individualized and helpful; and

(e) training specific to assigned job duties, such as, but not limited to, permissible assistance with medications, contraindications for medications that must be brought to the attention of appropriate individuals, assisting residents in transferring, ambulation, proper food preparation, proper performance of health maintenance activities if serving as a designated proxy caregiver and responding appropriately to dementia-related behaviors.

(4) **Trained Staff Present.** At least one staff person who has completed the minimum training requirements of Rule [111-8-63-.09\(2\)\(a\) through \(d\) and \(3\)\(a\) through \(e\)](#) above must be present in the assisted living community at all times any residents are present to provide necessary oversight and assistance to staff providing hands-on personal services who have not completed the training, to ensure that care and services are delivered safely and in accordance with these rules.

(5) **Training Hours Required During First Year of Employment.** All staff offering hands-on personal services to the residents, including the administrator or on-site manager, must satisfactorily complete a total of at least twenty-four (24) hours of continuing education within the first year of employment as a direct care worker. Staff providing hands-on personal services in a specialized memory care unit, must have 8 hours training related specifically to dementia care, included in their 24 hours of first-year employment training. The courses offered must be relevant to assigned job duties and include such topics as cardiopulmonary resuscitation and first aid certifications, utilizing standard precautions in working with aging residents, working with residents with Alzheimer's or other cognitive

impairments, working with persons who have developmental disabilities or persons who have mental illness, providing social and recreational activities, understanding legal issues, performing necessary physical maintenance, fire safety, housekeeping activities, recognizing and reporting abuse, neglect and exploitation, preparing and serving food safely, preserving the dignity and rights of residents receiving care to make meaningful choices, providing and documenting medication assistance, or other topics as determined necessary by the Department to support compliance.

(6) **Ongoing Staff Training.** Beginning with the second year of employment, staff providing hands-on personal services must have a minimum of sixteen (16) hours of job-related continuing education as referenced in paragraph [111-8-63-09\(5\)](#) above annually. For staff providing hands-on personal services in the memory care unit, at least two hours of the ongoing continuing education required each year must be devoted specifically to training relevant to caring for residents with dementia.

(7) **Training Records.** The community must maintain documentation reflecting course content, instructor qualifications, agenda and attendance rosters for all trainings provided.

(8) **Proxy Caregiver Training.** An assisted living community employing proxy caregivers must provide training to the proxy caregivers in accordance with the Rules and Regulations for Use of Proxy Caregivers, Chapter 111-8-100 subject to the limitation that only certified medication aides may administer medications on behalf of the community.

(9) **Hospice Training.** The assisted living community shall ensure that any medication aide(s) who will be administering liquid morphine to any hospice patient(s) residing in the community receive adequate training from a licensed hospice on the safe and proper administration of liquid morphine prior to such administration and on an annual basis thereafter. The community shall maintain documentation of all training provided.

(10) **Staff Health Examinations and Screenings.** The administrator, on-site manager, and each employee must have received a tuberculosis screening and a physical examination by a licensed physician, nurse practitioner or physician's assistant within twelve months prior to providing care to the residents. The physical examination must be sufficiently comprehensive to assure that the employee is physically qualified to work and free of diseases communicable within the scope of employment. Follow-up examinations must be conducted by a licensed physician, nurse practitioner or physician's assistant for each administrator or staff person to determine readiness to return to work following a significant illness or injury. Health information, screenings, assessments and medical releases regarding each staff member must be retained in a readily retrievable format by the assisted living community and made available for review and/or copying by Department representatives upon request.

(11) **Criminal History Background Checks for Owners Required.** The owner of the business or agency applying for the license must comply with the requirements of the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(12) **Criminal History Background Checks for Director, Administrator and Onsite Manager Required.** Prior to serving as a director, administrator or onsite manager of an assisted living community, the community must obtain a satisfactory fingerprint records check determination for the person to be hired in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(13) **Criminal History Background Checks for Direct Access Employees Required.** Prior to serving as a direct access employee, the community must obtain a satisfactory fingerprint records check determination for the person to be hired in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(14) The administrator or on-site manager must obtain an employment history for each employee and maintain documentation in the employee's file. If the potential employee has no prior employment history, then the assisted living community must retain documentation of a satisfactory personal reference check.

(15) Personnel files must be maintained in the assisted living community for each employee and for three years following the employee's departure or discharge. These files must be available for inspection by departmental staff

but must be maintained to protect the confidentiality of the information contained in them from improper disclosure. The files must include the following:

- (a) evidence of a satisfactory fingerprint record check determination, if applicable;
  - (b) report of physical examination completed by a licensed physician, nurse practitioner or physician's assistant, and a TB screening completed within the 12 months preceding the date of hire;
  - (c) evidence of trainings, skills competency determinations and recertifications as required by these rules and, if applicable, the Rules for Proxy Caregivers, Chapter 111-8-100;
  - (d) employment history, including previous places of work, employers and telephone contacts with previous employers;
  - (e) supporting documentation reflecting that the employee has the basic qualifications as represented, e.g. documentation of good standing by nursing board, no findings of abuse, neglect or exploitation entered against the individual in the nurse aide registry, satisfactory report of motor vehicle driving record where the employee may be transporting residents; and
  - (f) written evidence of satisfactory initial and annual work performance reviews for unlicensed staff providing hands-on personal care. Where the unlicensed staff perform specialized tasks, such as health maintenance activities, assistance with medications or medication administration, such performance reviews must include the satisfactory completion of skills competency checklists as specified in applicable rules. Such reviews must be conducted by staff or contractors qualified by education, training and experience to assess that the assigned duties are being performed in accordance with these rules and accepted health and safety standards.
- (16) Where the assisted living community permits a resident to hire his or her own companion-sitter, proxy caregiver to perform health maintenance activities or aide of any sort, the assisted living community must require assurance that the companion-sitter, proxy caregiver or aide so hired is familiar with emergency evacuation routes and has documentation reflecting compliance with the provisions of the Rules for Proxy Caregivers, Chapter 111-8-100, as applicable.
- (17) The administrator, on-site manager, and staff persons must not be under the influence of alcohol or other controlled substances while engaged in any work-related activity on behalf of the assisted living community.
- (18) The community must maintain a minimum on-site staff to resident ratio of one awake direct care staff person per 15 residents during waking hours and one awake direct care staff person per 25 residents during non-waking hours where the residents have minimal care needs. However, the assisted living community must staff above these minimum on-site staff ratios to meet the specific residents' ongoing health, safety and care needs.
- (a) Staff, such as cooks and maintenance staff, who do not receive on-going direct care training and whose job duties do not routinely involve the oversight or delivery of direct personal care to the residents, must not be counted towards these minimum staffing ratios. Personnel who work for another entity, such as a private home care provider, hospice, etc. or private sitters cannot be counted in the staff ratios for the assisted living community.
  - (b) At least one administrator, on-site manager, or a responsible staff person must be on the premises 24 hours per day providing supervision whenever residents are present.
  - (c) Residents must be supervised consistent with their needs.
- (19) Sufficient staff time must be provided by the assisted living community such that each resident:
- (a) receives services, treatments, medications and diet as prescribed;
  - (b) receives proper care to prevent decubitus ulcers and contractures;

- (c) is kept comfortable and clean;
- (d) is treated with dignity, kindness, and consideration and respect;
- (e) is protected from avoidable injury and infection;
- (f) is given prompt, unhurried assistance if she or he requires help with eating;
- (g) is given assistance, if needed, with daily hygiene, including baths and oral care; and
- (h) is given assistance in transferring and assisted self-preservation when needed.

(20) All persons, including the administrator or on-site manager, who offer direct care to the residents on behalf of the assisted living community, must maintain an awareness of each resident's normal appearance and must intervene, as appropriate, if a resident's state of health appears to be in jeopardy.

(21) All assisted living communities must develop and maintain accurate staffing plans that take into account the specific needs of the residents and monthly work schedules for all employees, including relief workers, showing planned and actual coverage for each day and night. The assisted living community must retain the completed staff schedules for a minimum of one year.

(22) Staff must wear employee identification badges which are readily visible with abbreviations for professional/special credentials displayed on the badges, if any.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-2-8](#), [31-2-9](#), [31-7-1](#) et seq., [43-26-12](#).

**HISTORY:** Original Rule entitled "Workforce Qualifications, Training and Staffing" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-63-10 Community Accountability**

- (1) The records required by these rules and other records maintained in the normal course of the business of the community must be available for inspection and review by properly identified representatives of the Department.
- (2) Where the Department identifies rule violations, the assisted living community will receive a written report of inspection. If the assisted living community disagrees with the facts and conclusions stated in the inspection report, it must submit its written statement explaining its disagreement and any evidence supporting the disagreement to the Department within 10 days of the receipt of the written inspection report. Where the Department concurs with the written statement of the assisted living community, it will issue a revised inspection report to the assisted living community.
- (3) Within 10 days of receipt of the written report of inspection, the assisted living community must develop a written plan for correcting any rule violations identified. The plan of correction must identify the specific actions that the assisted living community will take by date certain to come into compliance with each rule for which a deficient practice was identified.
- (4) A copy of the most recent inspection report and plan of correction must be displayed in the assisted living community in a location that is routinely used by the community to communicate information to residents and visitors. Additionally, if the community maintains a website, it shall post a web link in a prominent location on the main page of the website that provides access to copies of all inspection reports and plans of correction from the previous 18 months. When the Department develops a website for receiving plans of correction electronically and notifies the community of the appropriate internet address, the community also must file its plan of correction electronically on the Department's website within 10 days of receipt of the report of inspection.

- (5) The assisted living community must take the corrective actions necessary to achieve compliance with the rules.
- (6) The assisted living community must complete and maintain an accurate and current licensed residential care profile on file with the Department when the Department makes available a system for the submission and collection of such information electronically.
- (7) The assisted living community must provide services that are consistent with the information reported on its licensed residential care profile, its license and these rules.
- (8) The assisted living community's marketing materials must be consistent with its licensure classification as an assisted living community, the information reported on its licensed residential care profile, and these rules.
- (9) Only an assisted living community licensed pursuant to these rules may hold itself out as offering assisted living care.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-2-8](#), [31-7-1](#) et seq.

**HISTORY:** Original Rule entitled "Community Accountability" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

### **111-8-63-.20 Medications**

- (1) **Self-Administration of Medications.** Residents who have the cognitive and functional capacities to engage in the self-administration of medications safely and independently without staff assistance or supervision must be allowed to store their own medications securely and self-administer medications if they so desire.
- (2) **Assistance with Self-Administration.** An assisted living community must provide assistance with or supervision of self-administered medications to those residents who have the cognitive capacity to engage in the self-administration of medications, but require or request staff assistance with or supervision of the self-administration of medications for safety or convenience.
- (a) Such staff assistance with or supervision of self-administered medications may only be provided for unit or multi-dose packaged medications prescribed for the particular resident and may include only the following tasks:
1. taking the medication, in its previously dispensed, properly labeled container, from where it is stored, and bringing the medication to the resident;
  2. reading the label, opening the container, removing a prescribed amount of medication from the container, and closing the container, in the presence of the resident;
  3. placing an oral dosage in the resident's hand or placing the dosage in another container where the resident requests assistance;
  4. applying topical medications;
  5. returning the medication container to proper secured storage; and
  6. assisting the resident's use of an EPI pen where the resident has known severe allergies for which an EPI pen has been prescribed on condition that there is an established written protocol detailing how it is to be used and when. The protocol must include immediately calling Emergency Services, 911, after any use of the EPI pen.
- (b) Staff assisting with or supervising self-administration of medications must be proficient in English and able to read, write and follow written instructions in English.

(3) **Community Administration of Medications.** Where the residents either are not capable of self-administration of medications or choose not to self-administer medications with assistance or supervision, the assisted living community must provide medication administration services to the residents in accordance with physicians' orders, the needs of the residents and these rules.

(4) **Specialized Staffing for Medication Administration.** The assisted living community offering medication administration services must employ certified medication aides, at a minimum, to administer medications.

(5) **Certified Medication Aide Requirements.** An assisted living community using certified medication aides to administer specific medications must do all of the following:

(a) **Check the Registry.** Ensure that the medication aides employed in the community are listed in good standing on the Georgia Certified Medication Aide Registry and have no record of being terminated for cause relating to the performance of medication aide tasks before permitting the aides to administer medications.

(b) **Administer Skills Competency Checks.** Determine and document that the medication aides who have been certified for more than one year upon hiring, continue to have the knowledge and skills necessary to administer medications properly for the particular community. The community must use a skills competency checklist which meets the requirements contained in the standardized clinical skills competency checklist used to certify medication aides.

(c) **Quarterly Observations.** Use a licensed registered professional nurse or a pharmacist to conduct quarterly random medication administration observations to determine that the aides are administering medications correctly and in compliance with these rules and report any issues to the assisted living community administration for resolution.

(d) **Quarterly Drug Regimen Reviews.** Secure the services of a licensed pharmacist to perform all of the following duties:

1. Conduct quarterly reviews of the drug regimen for each resident of the assisted living community and report any irregularities to the assisted living community administration.

2. Remove for proper disposal any drugs that are expired, discontinued or in a deteriorated condition or where the resident for whom such drugs were ordered is no longer a resident.

3. Establish or review policies and procedures for safe and effective drug therapy, distribution, use and control.

4. Monitor compliance with established policies and procedures for medication handling and storage.

(e) **Authorized Tasks for Certified Medication Aides.** An assisted living community may allow a certified medication aide to do only the following tasks related the administration of medications utilizing only unit or multidose packaging of medications:

1. Administer physician ordered oral, via a feeding tube, ophthalmic, topical, otic, nasal, vaginal and rectal medications.

2. Administer insulin, epinephrine, and B12 pursuant to physician direction and protocol.

3. Administer medications via a metered dose inhaler.

4. Conduct finger stick blood glucose testing following established protocol.

5. Administer a commercially prepared disposable enema ordered by a physician.

6. Assist residents in the supervision of self-administration of medications.

7. Administer liquid morphine to a resident of the community who is the patient of a licensed hospice, pursuant to a hospice physician's written order that contains specific instructions for indication, dosage, frequency and route of administration.

(f) **Annual Competency Reviews.** Complete comprehensive clinical skills competency reviews for each certified medication aide utilizing the skills competency checklist at least, annually after hiring to determine that the aides continue to have the necessary skills to perform the medication tasks assigned competently. Such skills competency checklists must be administered by Georgia-licensed registered nurses, pharmacists or physicians, who indicate in writing that the tasks observed are being performed competently.

(g) **Proper Notice of Separation for Cause.** Ensure that where a medication aide is terminated for cause relating to the performance of medication aide tasks, the aide is provided with the following:

1. a separation notice that clearly describes the facts that support the termination for cause;
2. written notice that being terminated for cause related to the administration of medications, if not successfully appealed through a hearing on right to unemployment benefits will result in the loss of good standing on the Georgia Certified Medication Aide Registry; and
3. the loss of good standing on the Certified Medication Aide Registry will make the aide ineligible for hiring as a certified medication aide by another assisted living community.

(h) **Registry Notification.** Submit to the Georgia Certified Medication Aide Registry a copy of the Separation Notice for the certified medication aide only if the separation related specifically to the performance of medication aide tasks and the termination for cause has either been finally upheld by the Department of Labor or the time for appealing the Separation Notice has expired.

(6) **Communities Conducting Certified Medication Aide Training.** A community choosing to provide a certified medication aide training program must do all of the following:

- (a) Utilize the state-approved medication aide training program ensuring that the training is administered by a Georgia-licensed registered nurse, pharmacist, or physician.
- (b) Require the aide to demonstrate the requisite clinical skills to serve as a medication aide before a Georgia-licensed registered nurse, pharmacist or physician utilizing the standardized medication administration checklist developed by the Department.
- (c) Prepare the aide to take the written competency examination to become a certified medication aide.
- (d) Verify that the aide is in good standing on the Georgia certified nurse aide registry.
- (e) Provide information to the aide on the registration and locations for taking the written competency examination.
- (f) Provide the documentation to the Georgia Certified Medication Aide Registry that is necessary to complete the application for placement of the aide's name on the Georgia Certified Medication Aide Registry.
- (g) Not permit the aide to administer medications independently unless the aide is listed on the Georgia certified medication aide registry in good standing.

(7) **Basic Medication Training for Staff Assisting with Self-Administration.** The assisted living community must provide and document medication training for the unlicensed staff who are not certified medication aides but who are providing assistance with or supervision of self-administration of medications to capable residents. The medication training must be conducted with an appropriate curriculum for providing medication assistance and include at least the following topics:

- (a) the assisted living community's medication policy and procedures, including actions to take if concerns regarding resident's capacity to self-administer medications are identified;
- (b) how to read prescription labels including common abbreviations;
- (c) providing the right medication to the right resident at the right time in the right amount and the right way including how to measure various medications;
- (d) actions to take when concerns regarding medications are identified;
- (e) infection control procedures relative to providing assistance with medications;
- (f) proper medication storage and disposal;
- (g) recognition of side effects and adverse reactions for the specific medications;
- (h) understanding the common classifications of medications, typical side effects and adverse reactions and medications for which unlicensed staff may never provide assistance with or supervision of self-administration; and
- (i) proper documentation and record keeping using the Medication Assistance Record.

**(8) Medication Skills Competency Determinations.** Unlicensed staff who are not certified as medication aides providing assistance with or supervision of self-administered medications must demonstrate when hired and at least, annually thereafter, the necessary skills to perform the medication tasks assigned competently by completing skills competency checklists before appropriately trained community staff.

**(9) Maintaining Records on Medication Assistance and Administration.** Where the assisted living community either provides assistance with, or supervision of self-administered medications or administers medications to residents, the community must maintain a daily Medication Assistance Record (MAR) for each resident who receives assistance or administration. The MAR must include the name of the specific resident, any known allergies, the name and telephone number of the resident's health care provider, the name, strength and specific directions including key side effects and adverse reactions for use of each medication and a chart for staff who provide assistance or administration to record initials, time and date when medications are taken, refused or a medication error is identified (e.g. missed dosage). The staff providing the assistance or administration of medications must update the MAR each time the medication is offered or taken.

- (a) The assisted living community must make medication information concerning the descriptions of medication, dosing, side effects, adverse reactions and contraindications for each medication being administered to the residents immediately available for reference by staff providing medication assistance or administration.
- (b) Staff of the assisted living community providing assistance with or administration of medications must document in the resident's record any unusual reactions to the medications and provide such information to the resident, the resident's representative and the health care provider as appropriate.
- (c) For any administration of liquid morphine by a certified medication aide, staff shall observe and document the following in the resident's record:
  1. the resident's need for PRN liquid morphine, including but not limited to verbalizations of pain, groaning, grimacing or restlessness;
  2. the date, time and location of the initial dose administered by a licensed hospice health care professional;
  3. the dosage, time and route of administration for the morphine administered in the community;
  4. the training provided by the licensed hospice; and

5. information regarding the special circumstances under which the hospice was unavailable to administer the medication.

(10) **Orders Required for All Medications.** An assisted living community must not allow its staff to assist with, provide supervision of self-administered medications or administer any medications, including over-the-counter medications, unless there is a physician's order specifying clear instructions for its use on file for the resident.

(11) **Timely Management of Medication Procurement.** Where the assisted living community procures medications on behalf of the residents, the community must obtain new prescriptions within 48 hours of receipt of notice of the prescription or sooner if the prescribing physician indicates that a medication change must be made immediately. If the pharmacy does not have the medication needed for the immediate change, available and has not obtained further directions from the physician, the community must notify the physician of the unavailability of the prescription and request direction. Refills of prescribed medications must be obtained timely so that there is no interruption in the routine dosing. Where the assisted living community is provided with a new medication for the resident, the MAR must be modified to reflect the addition of the new medication within 48 hours or sooner if the prescribing physician indicates that the medication change must be made immediately.

(12) **Storage and Disposal of Medications.** Medications must be stored securely and inventoried appropriately to prevent loss and unauthorized use. Medications must be stored under lock and key at all times whether kept by a resident or kept by the assisted living community for the resident, unless the medication is required to be kept by the resident on his or her person or staff member in close attendance due to the need for physician-prescribed frequent or emergency use. Additionally, for controlled substances, the secure storage must be a locked cabinet or box of substantial construction and a log must be maintained and updated daily by the community to account for all inventory.

(a) Duplicate keys for all medication storage containers must be available on site for appropriate use.

(b) Medications must be kept in original containers with original labels intact.

(c) Medications must be properly labeled in separate unit or multi-unit dose packaging and handled in accordance with physician's instructions, and laws and regulations applicable to the medications.

(d) The assisted living community must ensure that it properly disposes of unused medications using the current U.S. Food and Drug Administration or U.S. Environmental Protection Agency guidelines for the specific medications.

(e) The supply of liquid morphine on site shall be limited to 50 ml for each hospice patient in the community for which there is a physician's order for such medication.

**AUTHORITY:** O.C.G.A. §§ [31-2-7](#), [31-2-8](#), [31-7-1](#) et seq.

**HISTORY:** Original Rule entitled "Medications" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

**Amended:** F. Feb. 28, 2020; eff. Mar. 19, 2020.

# Department 160. RULES OF GEORGIA DEPARTMENT OF EDUCATION

## Chapter 160-1.

### Subject 160-1-4. GRANT PROGRAMS

#### 160-1-4-.270 Teacher Quality Advanced Placement Grant

1. **Purpose of the Grant.** The purpose of the grant is to support local educational agencies' (LEAs) efforts to improve the academic achievement of students and to increase access to college-level courses across the state. The Advanced Placement (AP) Teacher Training Grant will provide financial support for teachers to receive training during the summer of each year funded. This will allow schools to implement these Advanced Placement (AP) courses during the first or second year following training.

2. **Terms and Conditions.** Grants are awarded through a competitive process to LEAs. An LEA may apply for a grant to fund AP teacher training in up to two courses per school. Funding is to partially or fully cover the costs of training expenses, including registration, travel (based on current state rate per mile), meals, and lodging, if necessary. The grant award may not be used for supplies, classroom resources, or stipends. The grant may only be used to train classroom teachers, not administrators. An LEA that is selected as a grant recipient must commit to ensuring that:

- Teachers participate in training for eligible courses during the summer following the grant award.
- Selected schools will offer the AP courses for which the teachers received training in the next school year.

3. **Eligible Recipients.** All LEAs are eligible to apply. LEAs that have not utilized at least 80% of their Title II-A AP Teacher Training Grant funds in previous fiscal year are ineligible.

4. **Criteria for Award.** The Georgia Department of Education will convene a panel and facilitate the review of each application. Applications will be ranked based on the number of AP courses offered at each high school and the number of students currently scheduled in AP courses for the school year.

5. **Directions and Deadlines for Applying.** Announcements for grant applications will be sent to the Superintendent and AP Coordinator for each LEA. All application packets must be received electronically by the Georgia Department of Education on or before the date specified. The application packet will provide application dates and portal information for application submission. For questions regarding the Advanced Placement Teacher Training Grant, please contact the Program Manager, College Readiness and Talent Development at the Georgia Department of Education.

**AUTHORITY:** O.C.G.A. § [20-2-240](#).

**HISTORY:** Original grant description entitled "Teacher Quality Advanced Placement Grant" submitted Apr. 4, 2006.

**Submitted:** Nov. 2, 2006.

**Submitted:** Feb. 12, 2020.

# Department 160. RULES OF GEORGIA DEPARTMENT OF EDUCATION

## Chapter 160-4.

### Subject 160-4-2. DIVISION OF GENERAL INSTRUCTION

#### 160-4-2-.48 High School Graduation Requirements for Students Enrolling in the Ninth Grade for the First Time in the 2008-09 School Year and Subsequent Years

(1) **PURPOSE.** This rule specifies programs of study that shall be offered by local boards of education for students enrolling in the ninth grade for the first time in the 2008-2009 School Year and for subsequent years.

(2) **DEFINITIONS.**

(a) **Alternate Diploma** - the document awarded to students with the most significant cognitive disabilities who were assessed using the alternate assessment aligned to alternate academic achievement standards. While this diploma is standards-based and aligned with the state requirements for the regular high school diploma, it is not a regular high school diploma. Therefore, an alternate diploma does not terminate Free and Appropriate Public Education (FAPE) for students with an Individualized Education Program (IEP).

(b) **Career, Technical and Agricultural Education (CTAE) Pathways** - Three elective units in a coherent sequence that includes rigorous content aligned with industry-related standards leading to college and work readiness in a focused area of student interest.

(c) **Core Courses** - courses identified as "c" or "r" in Rule [160-4-2-.20](#) List of State-Funded K-8 Subjects and 9-12 Courses.

(d) **Elective Courses** - any courses identified as "e" in Rule [160-4-2-.20](#) List of State-Funded K-8 Subjects and 9-12 Courses that a student may select beyond the core requirements to fulfill the unit requirements for graduation.

(e) **Georgia Alternate Assessment (GAA)** - an alternate assessment based on alternate academic achievement standards. The GAA is a standardized, task-based assessment with multiple access points designed for students with significant cognitive disabilities under the Individuals with Disabilities Education Act (IDEA) whose Individualized Education Program (IEP) team has determined they are unable to meaningfully access the regular assessment program, even with maximum appropriate accommodations. The purpose of the GAA is to ensure that students with significant cognitive disabilities are provided access to the state academic content standards and given the opportunity to demonstrate achievement of the knowledge, concepts, and skills inherent in the standards.

(f) **Required courses** - specific courses identified as "r" in Rule [160-4-2-.20](#) List of State-Funded K-8 Subjects and 9-12 Courses that each student in a program of study shall pass to graduate from high school.

(g) **Secondary School Credential** - a document awarded to students at the completion of the high school experience.

1. **High School Diploma** - the document awarded to students certifying that they have satisfied attendance requirements, unit requirements and the state assessment requirements as referenced in Rule [160-3-1-.07](#) Testing Programs - Student Assessment.

2. **High School Certificate** - the document awarded to pupils who do not complete all of the criteria for a diploma or who have not passed the state assessment requirements as referenced in Rule [160-3-1-.07](#) Testing Programs - Student Assessment, but who have earned 23 units.

3. **Special Education Diploma** - the document awarded to students with disabilities assigned to a special education program who have not met the state assessment requirements referenced in Rule [160-3-1-.07](#) Testing Programs - Student Assessment or who have not completed all of the requirements for a high school diploma but who have nevertheless completed their IEP.

(h) **Significant Cognitive Disabilities** - students with significant intellectual disabilities or intellectual disabilities concurrent with motor, sensory or emotional/behavioral disabilities who require substantial adaptations and support to access the general curriculum and require additional instruction focused on relevant life skills and participate in the Georgia Alternate Assessment (GAA).

(i) **Unit** - one unit of credit awarded for a minimum of 150 clock hours of instruction or 135 hours of instruction in an approved block schedule.

(j) **Unit, Summer School** - one unit of credit awarded for a minimum of 120 clock hours of instruction.

**(3) REQUIREMENTS.**

(a) Local boards of education shall provide secondary school curriculum and instructional and support services that reflect the high school graduation and state assessment requirements and assist all students in developing their unique potential to function in society.

(b) Local boards of education shall require that:

1. Students who enroll from another state meet the graduation requirements for the graduating class they enter and the state assessment requirements as referenced in Rule [160-3-1-.07](#) Testing Programs - Student Assessment.

2. Students who enroll in the ninth grade for the first time in the 2008-2009 school year and withdraw shall meet the graduation requirements specified in this rule and the assessment requirements specified in Rule [160-3-1-.07](#) Testing Programs - Student Assessment.

**3. UNITS OF CREDIT.**

(i) All state-supported high schools shall make available to all students the required areas of study.

(ii) A course shall count only once for satisfying any unit of credit requirement for graduation. See the following chart.

**(iii) AREAS OF STUDY.**

|                            | <b>Units Required</b> |
|----------------------------|-----------------------|
| (I) English/Language Arts* | 4                     |
| (II) Mathematics*          | 4**                   |
| (III) Science*             | 4                     |

The 4<sup>th</sup> science unit may be used to meet both the science and elective requirement

|  |           |
|--|-----------|
| (IV) Social Studies*   | 3         |
| (V) CTAE and/or<br>Modern Language/Latin and/or<br>Fine Arts | 3         |
| (VI) Health and Physical Education*                          | 1         |
| (VII) Electives  | 4         |
| <b>TOTAL UNITS (MINIMUM)</b>                                 | <b>23</b> |

\*Required Courses and/or Core Courses

\*\* Students entering ninth grade in 2008-2009, 2009-2010, and 2010-2011 only, who earn credit in Mathematics I and Mathematics II or GPS Algebra and GPS Geometry, along with 2 additional core mathematics courses, will have satisfied the **minimum** mathematics requirements for high school graduation.

#### 4. COURSE CREDIT.

(i) Unit credit shall be awarded only for courses that include concepts and skills based on the Georgia Performance Standards (GPS) or Common Core Georgia Performance Standards (CCGPS) for grades 9-12 or those approved by the State Board of Education. Unit credit may be awarded for courses offered in the middle grades that meet 9-12 GPS or CCGPS requirements. The IEP, if applicable, shall specify whether core courses taken as part of an IEP shall receive core unit credit.

(ii) No course credit may be awarded for courses in which instruction is based on the GPS for grades K-8.

(iii) Completion of diploma requirements does not necessarily qualify students for the HOPE Scholarship Program.

#### 5. AREAS OF STUDY.

(i) Courses that shall earn unit credit are listed in Rule [160-4-2-.20](#) List of State-Funded K-8 Subjects and 9-12 Courses for Students Entering Ninth Grade in 2008 and Subsequent Years.

(ii) Any student may select any course listed in the course listing rule. The one exception to this provision is where the letter "r" appears with course names. These courses are required. They **must** be successfully completed and cannot be substituted with any other course. Any course identified as "c" is a core course and may be selected to count as one of the core unit requirements. A course identified as "e" is an elective course that may be selected beyond the core requirements to fulfill the unit requirements.

(I) **English Language Arts:** Four units of credit in English language arts shall be required of all students. A full unit of credit in American Literature/Composition and a full unit of credit in Ninth-Grade Literature and Composition shall be required. All courses that may satisfy the remaining units of credit are identified with a "c." The Writing, Conventions, and Listening, Speaking, and Viewing strands of the Georgia Performance Standards shall be taught in sequence in grades 9-12. Literature modules may be taught in any sequence in grades 10-12.

(II) **Mathematics:** Four units of core credit in mathematics shall be required of all students, including Mathematics I or GPS Algebra, or its equivalent and Mathematics II or GPS Geometry, or its equivalent and Mathematics III or GPS Advanced Algebra or its equivalent. Additional core courses needed to complete four credits in mathematics must be chosen from the list of GPS/ CCGPS/AP/IB/dual enrollment designated courses.

I. The mathematics requirements above apply to each student with a disability, consistent with his or her Individualized Education Program. Students with Disabilities who earn credit in Mathematics I or GPS Algebra and the associated mathematics support course, and Mathematics II or GPS Geometry and the associated mathematics support course, may upon determination through the Individualized Education Program Team meet mathematics diploma requirements by completing Mathematics III or GPS Advanced Algebra for a total of 3 mathematics core credits. Successful completion of 3 core units of mathematics may not meet the mathematics admission requirements for entrance into a University System of Georgia institution or other post-secondary institution without additional coursework.

II. All students, including students with disabilities, who enter ninth grade in 2008-2009, 2009-2010, and 2010-2011, only and who earn core credit in Mathematics I and Mathematics II or GPS Algebra and GPS Geometry, along with 2 other core mathematics courses, will have satisfied the minimum mathematics requirements for high school graduation. Mathematics Support I, GPS Algebra Support I, Mathematics Support II, GPS Geometry Support II, and Mathematics Support III, and GPS Advanced Algebra Support III may be designated as elective or core courses for students who entered ninth grade in 2008-2009, 2009-2010, 2010-2011. Students who complete Mathematics I and Mathematics II or GPS Algebra and GPS Geometry, along with 2 other core mathematics

courses, but who do not complete Mathematics III or GPS Advanced Algebra, may not meet the mathematics admission requirements for entrance into a University System of Georgia institution or other post-secondary institutions without additional coursework.

(III) **Science:** Four units of credit in science shall be required of all students, including one full unit of Biology; one unit of either Physical Science or Physics; one unit of either Chemistry, Earth Systems, Environmental Science or an AP/IB course; and one additional science unit. The fourth science unit may be used to meet both the science and elective requirements. Any AP/IB science course may be substituted for the appropriate courses listed above.

(IV) **Social Sciences:** Three units of credit shall be required in social studies. One unit of credit shall be required in United States History. One unit of credit shall be required in World History. One-half unit of American Government/Civics shall be required. One-half unit of Economics shall be required.

(V) **CTAE/Modern Language/Latin/Fine Arts:** A total of three units of credit shall be required from the following areas: CTAE and/or Modern Language/Latin and/or Fine Arts. Students are encouraged to select courses in a focused area of interest.

**I. Career, Technical and Agricultural Education (CTAE) Pathways:** Students may earn three units of credit in a coherent sequence of CTAE courses through a self-selected pathway leading to college readiness and a career readiness certificate endorsed by related industries.

**II. Modern Language/Latin:** All students are encouraged to earn two units of credit in the same modern language/Latin. Students planning to enter or transfer into a University System of Georgia institution or other post-secondary institution must take two units of the same modern language/Latin. Technical College System of Georgia institutions do not require modern language/Latin for admissions.

A. Students whose native language is not English may be considered to have met the foreign language expectation by exercising the credit in lieu of enrollment option if they are proficient in their native language. A formal examination is not necessary if other evidence of proficiency is available.

B. American Sign Language may be taken to fulfill the modern language requirements.

**III. Fine Arts:** Electives may be selected from courses in fine arts.

(VI) **Health and Physical Education:** One unit of credit in health and physical education is required. Students shall combine one-half or one-third units of credit of Health (17.011), Health and Personal Fitness (36.051), or Advanced Personal Fitness (36.061) to satisfy this requirement. Three (3) units of credit in JROTC (Junior Reserve Officer Training Corps) may be used to satisfy this requirement under the following conditions:

1) JROTC courses must include Comprehensive Health and Physical Education Rule requirements in rule [160-4-2-.12](#) and

2) the local Board of Education must approve the use of ROTC courses to satisfy the one required unit in health and physical education.

## **6. REQUIRED PROCEDURES FOR AWARDING UNITS OF CREDIT.**

(i) A unit of credit for graduation shall be awarded to students only for successful completion of state-approved courses of study based on a minimum of 150 clock-hours of instruction provided during the regular school year, 135 clock-hours of instruction in an approved block schedule during the regular school year, or a minimum of 120 clock-hours of instruction in summer school.

## **7. STUDENTS WITH SIGNIFICANT COGNITIVE DISABILITIES.**

(i) Students with significant cognitive disabilities who entered the ninth grade for the first time prior to the 2020-2021 school year may graduate and receive a regular high school diploma when the student's IEP team determines that the student has:

(I) completed an integrated curriculum based on the GPS that includes instruction in Mathematics, English/Language Arts, Science and Social Studies as well as career preparation, self determination, independent living and personal care to equal a minimum of 23 units of instruction, and

(II) participated in the GAA during middle school and high school, and

(III) reached the 22<sup>nd</sup> birthday OR has transitioned to an employment/education/training setting in which the supports needed are provided by an entity other than the local school system.

(ii) Students with significant cognitive disabilities who entered the ninth grade for the first time on or after the 2020-2021 school year may graduate and receive an alternate diploma when the student's IEP team determines that the student has:

(I) completed an integrated curriculum based on the Georgia Standards of Excellence (GSE) that includes instruction in Mathematics, English/Language Arts, Science and Social Studies as well as career preparation, self-determination, independent living and personal care to equal a minimum of 23 units of instruction, and

(II) participated in the GAA during middle school and high school, and

(III) has transitioned to an employment/education/training setting in which the supports needed are provided by an entity other than the local school system.

## 8. LOCAL AUTHORITIES AND RESPONSIBILITIES.

(i) Local boards of education shall provide instructional, support and delivery services. These services shall include, but are not limited to, the following:

(I) A continuous guidance component beginning in middle school. The purposes of the guidance component are to familiarize students with graduation requirements, to help them identify the likely impact of individual career objectives on the program of studies they plan to follow and to provide annual advisement sessions to report progress and offer alternatives in meeting graduation requirements and career objectives.

(II) Record keeping and reporting services that document student progress toward graduation and include information for the school, parents and students.

(III) Diagnostic and continuous evaluation services that measure individual student progress in meeting competency expectations for graduation.

(IV) Instructional programs, curriculum and course guides and remedial opportunities to assist each student in meeting graduation requirements.

(V) Appropriate curriculum and assessment procedures for students who have been identified as having disabilities that prevent them from meeting the prescribed competency performance requirements.

**AUTHORITY:** O.C.G.A. §§ [20-2-131](#); [20-2-140](#); [20-2-142](#); [20-2-150\(a\)](#); [20-2-151\(a\)](#); (b); [20-2-154\(a\)](#); [20-2-160](#); [20-2-161.1](#); [20-2-161.2](#); [20-2-281\(a\)](#), (c).

**HISTORY:** Original Rule entitled "High School Graduation Requirements for Students Enrolling in the Ninth Grade for the First Time in the 2008-09 School Year and Subsequent Years" adopted. F. Sept. 13, 2007; eff. Oct. 3, 2007.

**Amended:** F. Jul. 21, 2011; eff. Aug. 10, 2011.

**Amended:** F. Feb. 20, 2020; eff. Mar. 11, 2020.

# Department 195. GEORGIA BOARD FOR HEALTH CARE WORKFORCE

## Chapter 195-1. ADMINISTRATION

### 195-1-.01 General Definitions

(1) "Georgia Board of Health Care Workforce" means the organization and its office, formerly known as the Joint Board of Family Practice, redesignated under Ga. Laws 1998, Act 785 (SB 533), and governed by Title 49 Chapter 10 of the Official Code of Georgia Annotated as amended to address the physician workforce needs of Georgia communities through the support and development of medical education programs and to administer such grants and programs as may be funded from time to time by the Georgia General Assembly relating to the education and training of physicians.

(2) "Board" means the members serving a term of office on Georgia Board of Health Care Workforce. The Board shall be composed of 15 members, all of whom are residents of Georgia.

(a) Four members shall be primary care physicians, at least two of whom shall be from rural areas, four members shall be physicians who are not primary care physicians, at least two of whom shall practice in rural areas, three members shall be representatives of hospitals which are not teaching hospitals, with at least two of those members being a representative of a rural, nonprofit hospital, and two of such members shall be physicians; one member shall be a dentist; one member shall be a physician assistant; one member shall be a nurse practitioner; and one member shall have no connection with the practice of medicine or the provision of health care. The physicians on the Board shall represent a diversity of medical disciplines including, but not limited to, women's health, geriatrics and children's health and to the greatest extent possible, shall be in the active practice of medicine providing direct patient care. The Board shall represent the gender, racial, and geographical diversity of the state.

(b) All members shall be appointed by the Governor and confirmed by the Senate. All members of the board in office on July 1, 2019, shall continue to serve as a member of the board until the expiration of his or her term of office.

1. Successors to members shall be appointed for terms of six years. All members shall serve until their successors are appointed and qualified. Members appointed shall be eligible to serve on the Board until confirmed by the Senate at the session of the General Assembly next following their appointment.

(c) In the case of a vacancy on the Board by reason of death or resignation of a member or for any other cause other than the expiration of the member's term of office, the Board shall by secret ballot elect a temporary successor. If the General Assembly is in session, the temporary successor shall serve until the end of that session. If the General Assembly is not in session, the temporary successor shall serve until the end of the session next following the vacancy or until the expiration of the vacated member's term of office, whichever occurs first. The Governor shall appoint a permanent successor who shall be confirmed by the Senate. The permanent successor shall take office on the first day after the General Assembly adjourns and shall serve for the unexpired term and until his or her successor is appointed and qualified.

(3) The "Executive Director" is the chief administrative officer of the Board and directs the day-to-day operations of its office. The Executive Director is charged to perform all the duties and responsibilities delegated by the Board.

(4) "Standing Committee" means a committee performing a continuous function which will remain in existence permanently or for the life of the assembly that establishes it.

(5) "Special Committee" means a committee organized to carry out a specific task, which at the completion of said task, shall no longer exist.

(6) "Annual Meeting" means the first meeting of the Board after the beginning of the Fiscal Year and at which a quorum is present.

(7) "Georgia Resident" means to qualify as a resident of the state of Georgia for the purpose of participation in the Medical Student Capitation Program, or other Board program where appropriate, an entering freshman student must show he/she has been a legal resident of Georgia for a period of at least twelve months prior to certification of residency. In the event a student is identified as a potential participant after beginning a program of study, the student must demonstrate he/she was a legal resident of Georgia for a period of one year prior to entering the medical school. A Certification of Residency Form, as defined by the "Georgia Board of Health Care Workforce", must be completed. This Form shall be notarized and signed by a judge of the highest court of the county where a student maintains his/her legal residence. Completion of this Form shall constitute sufficient proof of Georgia residency status.

**AUTHORITY: O.C.G.A. §§ 49-10, 49-10-6.**

**HISTORY:** Original Rule entitled "General Definitions" adopted. F. Aug. 25, 1978; eff. Sept. 14, 1978.

**Amended:** F. Aug. 14, 1979; eff. Sept. 3, 1979.

**Amended:** F. Sept. 4, 1981; eff. Sept. 24, 1981.

**Amended:** F. Feb. 12, 1985; eff. Mar. 4, 1985.

**Amended:** F. Oct. 9, 1986; eff. Oct. 29, 1986.

**Amended:** F. Feb. 12, 1998; eff. Mar. 4, 1998.

**Amended:** F. Dec. 14, 1999; eff. Jan. 3, 2000.

**Amended:** F. Mar. 13, 2000; eff. Apr. 2, 2000.

**Repealed:** New Rule of same title adopted. F. Jan. 10, 2005; eff. Jan. 30, 2005.

**Repealed:** New Rule of same title adopted. F. May 5, 2009; eff. May 25, 2009.

**Amended:** Aug. 13, 2013; eff. Sept 2, 2013.

**Repealed:** New Rule of same title adopted. F. Feb. 3, 2020; eff. Feb. 23, 2020.

# Department 266. GEORGIA EMERGENCY MANAGEMENT AGENCY

## Chapter 266-1. RESCUE ORGANIZATIONS (REPEALED)

### 266-1-.01 [Repealed]

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "The Act" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### 266-1-.02 [Repealed]

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Purpose" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### 266-1-.03 [Repealed]

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Definitions" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### 266-1-.04 [Repealed]

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "License" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### 266-1-.05 [Repealed]

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Local Authority for Establishing Local Rescue Organizations" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### 266-1-.06 [Repealed]

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Application for License" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### **266-1-.07 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Duties of the License Officer" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### **266-1-.08 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Renewal of License" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### **266-1-.09 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Revocation or Suspension of License" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### **266-1-.10 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Standards for Rescue Specialist" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### **266-1-.11 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Standards for Hazardous Materials Training for Rescue Specialist" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

### **266-1-.12 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Standards for Auto Extrication Training for Rescue Specialists" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.13 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Standards for Rescue Instructors" adopted. F. Mar. 16, 1994; off. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.14 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Special Skills" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.15 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Minimum Standards for Primary Rescue Vehicle and Equipment" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.16 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Special Interest Groups" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.17 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "General" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.18 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Enforcement" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

**266-1-.19 [Repealed]**

**AUTHORITY:** O.C.G.A. § [38-3-21](#).

**HISTORY:** Original Rule entitled "Penalty" adopted. F. Mar. 16, 1994; eff. Apr. 5, 1994.

**Repealed:** Feb. 6, 2020; eff. Feb. 26, 2020.

# Department 290. RULES OF DEPARTMENT OF HUMAN SERVICES

## Chapter 290-7. OFFICE OF CHILD SUPPORT RECOVERY

### Subject 290-7-1. RECOVERY AND ADMINISTRATION OF CHILD SUPPORT

#### 290-7-1-.17 Liens and Levies

(a) The Department is authorized to file a notice of lien against the real and personal property of any obligor who resides in or owns property in the state and owes past-due child support. Liens against personal property other than personal property subject to a certificate of title, shall be filed with the office of the Secretary of State. Upon the filing of the notice, a lien arises by operation of law.

(b) The Department has the authority to levy and seize a deposit or account (meaning a demand deposit account, checking or negotiable order of withdrawal account, savings account, time deposit account, or a money market mutual fund account) of any obligor who is in arrears in an amount equal to at least the support payment for one month from any financial institution (meaning every federal or state-chartered commercial or savings bank, including savings and loan associations and cooperative banks, federal or state-chartered credit unions, benefit associations, insurance companies, safe-deposit companies, trust companies, and any money market mutual fund).

(c) If the child support order contains notice that the obligor is subject to the provisions of O.C.G.A. §§ [19-11-32](#) through [19-11-39](#), or the Department has previously sent the obligor a notice by regular mail to the last known address of the obligor referencing these same code sections, further notice is not required prior to levying on the deposit or account.

(d) At the time the notice of levy is sent to the financial institution, the Department must notify the obligor and any obligee a notice of the impending levy via a writing containing the warnings required by O.C.G.A. § [19-11-36](#).

(e) An obligor or an account holder of interest wishing to contest the levy must send the Department a written challenge within ten business days of the date of the notice to the obligor. The obligor or any account holder of interest who makes a timely challenge to the levy under this Rule is entitled to a hearing in the superior court in which the underlying support order was entered or registered.

(f) The Department may reverse the levy prior to such hearing if its internal review following receipt of the challenge indicates that a mistake in identity has occurred or the obligor is not delinquent in an amount equal to the payment for one month.

(g) The Department is also authorized to assert liens against any tangible and intangible property, whether real or personal, and any interest in property, whether legal or equitable, belonging to the obligor. Any property acquired by the obligor after the child support lien arises shall also be subject to such lien. The Department is further authorized to offset against worker's compensation awards and lottery winnings.

(h) The state IV-D agency of another state may determine that a noncustodial parent holds assets in a financial institution doing business in the State of Georgia. Full faith and credit shall be given to liens arising from any judicial or administrative action in another state or foreign jurisdiction. That state IV-D agency may send the levy directly to the financial institution in Georgia asking that it surrender the funds directly to that state IV-D agency. If the financial institution refuses to do so, the state IV-D agency may then send a UIFSA enforcement transmittal to the Department for enforcement.

(i) If it is determined that the noncustodial parent in a Georgia case holds assets in a financial institution outside of Georgia, the Department may send the levy directly to the financial institution doing business in that state or foreign jurisdiction. A request shall be made that the funds be surrendered to the Department. However, if the financial

institution refuses to remit the money or the obligor does not reside within Georgia and wishes to challenge the intergovernmental levy, the Department shall release the levy and send a UIFSA enforcement transmittal to the IV-D agency of the state or foreign jurisdiction where the obligor resides.

**AUTHORITY:** O.C.G.A. §§ [19-11-18](#), [19-11-30.2](#) through [19-11-37](#).

**HISTORY:** Original Rule entitled "Recovery of Fees" adopted. F. Oct. 17, 1991; eff. Nov. 6, 1991.

**Repealed:** New Rule of same title adopted. F. July 23, 2004; eff. Aug. 12, 2004.

**Repealed:** New Rule entitled "Liens and Levies" adopted. F. June 15, 2011; eff. July 5, 2011.

**Note:** Correction of typographical error in paragraph (b) on SOS Rules and Regulations website only. In accordance with the Official Compilation Rules and Regulations of the State of Georgia (effective July 5, 2011), "The Department has the to levy and seize a deposit or account." corrected to "The Department has the authority to levy and seize a deposit or account.", as requested by the Agency. Effective February 24, 2020.

# Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

## Chapter 391-2. COASTAL RESOURCES

### Subject 391-2-4. SALTWATER FISHING REGULATIONS

#### 391-2-4-.04 Saltwater Finfishing

(1) **Purpose.** The purpose of these Rules is to implement the authority of the Board of Natural Resources to promulgate rules and regulations based on sound principles of wildlife research and management, establishing the seasons, methods of fishing, and disposition; size, possession, and creel limits; and gear and landing specifications for certain finfish.

(2) **Definitions.**

(a) "Daily creel limit" means the lawful amount of a species of finfish that a person may take in one day or possess at any one-time, except at one's place of abode or at a commercial storage facility provided the Board has not prohibited sale of that species.

(a.1) "Landed" means to bring fish to shore in this state, regardless of the jurisdiction from which they were taken or harvested.

(b) "Minimum size" means the species' specific size in length, specified as fork length, lower jaw fork length or total length, below which size it is unlawful to possess that finfish species.

(b.1) "Maximum size" means the species' specific size in length, specified as fork length, lower jaw fork length or total length, above which size it is unlawful to possess that finfish species.

(c) "Open Season" means that specified period of time during which one may take from any of the waters of this state certain finfish species.

(d) "Sharks" means all species of sharks other than those comprising the small shark composite as defined in subparagraph 2(e), hammerhead sharks as defined in subparagraph 2(g), prohibited sharks as defined in subparagraph 2(h), and individual species regulated by this rule.

(e) "Small Shark Composite" means a group of sharks inclusive of Atlantic sharpnose shark (*Rhizoprionodon terraenovae*), bonnethead (*Sphyrna tiburo*), and spiny dogfish (*Squalus acanthias*).

(f) "Handline" means a mainline to which no more than two hooks are attached and which is retrieved by hand without the aid of mechanical devices.

(g) "Hammerhead Sharks" means a group of sharks inclusive of great hammerhead (*Sphyrna mokarran*), scalloped hammerhead (*Sphyrna lewini*) and smooth hammerhead (*Sphyrna zygaena*).

(h) "Prohibited Sharks" means a group of sharks inclusive of sand tiger (*Carcharias taurus*), sandbar shark (*Carcharhinus plumbeus*), silky shark (*Carcharhinus falciformis*), bigeye sandtiger (*Odontaspis noronhai*), whale shark (*Rhincodon typus*), basking shark (*Cetorhinus maximus*), white shark (*Carcharodon carcharias*), dusky shark (*Carcharhinus obscurus*), bignose shark (*Carcharhinus altimus*), Galapagos shark (*Carcharhinus galapagensis*), night shark (*Carcharhinus signatus*), reef shark (*Carcharhinus perezii*), narrowtooth shark (*Carcharhinus brachyurus*), Caribbean sharpnose shark (*Rhizoprionodon porosus*), smalltail shark (*Carcharhinus porosus*), Atlantic angel shark (*Squatina dumeril*), longfin mako (*Isurus paucus*), bigeye thresher (*Alopias superciliosus*), sharpnose

sevengill shark (*Hepttranchias perlo*), bluntnose sixgill shark (*Hexanchus griseus*), bigeye sixgill shark (*Hexanchus nakamurai*), and oceanic whitetip shark (*Carcharhinus longimanus*).

(3) **Seasons, Daily Creel and Possession Limits, Minimum and Maximum Size Limits.** The following species may be taken in accordance with the seasons, daily creel and possession limits, and minimum and maximum size limits set forth below, except as otherwise specifically provided herein:

| SPECIES   | SEASON   | Daily Creel and Possession Limit         | Minimum Size (inches) | Maximum Size (inches) |
|---|--|--|-----------------------|-----------------------|
| (a) Amberjack   | All Year   | 1  | 28 FL                 |                       |
| (b) Atlantic croaker  | All Year   | 25                                       |                       |                       |
| (c) Atlantic sturgeon   | No Open Season has been established by the Board of Natural Resources. |  |                       |                       |
| (d) Black drum  | All Year   | 15                                       | 14 TL                 |                       |
| (e) Black sea bass  | All Year   | 15                                       | 12 TL                 |                       |
| (f) Blue marlin   | No Open Season has been established by the Board of Natural Resources. |  |                       |                       |
| (g) Bluefish  | All Year   | 15                                       | 12 TL                 |                       |
| (h) Cobia   | March 1 - October 31   | 1 per person not to exceed 6 per boat    | 36 FL                 |                       |
| (i) Dolphin   | All Year   | 10 per person not to exceed 60 per boat. | 20 FL                 |                       |
| 1. Headboats with a valid certificate of inspection are allowed 10 dolphin per paying passenger.  |  |  |                       |                       |
| (j) Flounder (Paralichthys spp.)  | All Year   | 15                                       | 12 TL                 |                       |
| (k) Gag grouper   | All Year   | 2  | 24 TL                 |                       |
| (l) King mackerel   | All Year   | 3  | 24 FL                 |                       |
| (m) Red Drum  | All Year   | 5  | 14 TL                 | 23 TL                 |
| (n) Red Porgy   | All Year   | 3  | 14 TL                 |                       |
| (o) Red Snapper   | All Year   | 2  | 20 TL                 |                       |
| (p) Sailfish  | No Open Season has been established by the Board of Natural Resources. |  |                       |                       |
| (q) Prohibited Sharks   | Unlawful to possess.   |  |                       |                       |
| (r) Sharks  | All Year   | 1 per person or boat                     | 54 FL                 |                       |
| (s) Sheepshead  | All Year   | 15                                       | 10 TL                 |                       |
| (t) Small Shark Composite   | All Year   | 1  | 30 FL                 |                       |
| (u) Spanish mackerel  | All Year   | 15                                       | 12 FL                 |                       |
| 1. A catch of Spanish mackerel under the minimum size limit is allowed equal to five percent by weight of the total catch of Spanish mackerel on board a trawler. |  |  |                       |                       |
| (v) Spot  | All Year   | 25                                       |                       |                       |
| (w) Spotted sea trout   | All Year   | 15                                       | 14 TL                 |                       |
| (x) Tarpon  | All Year   | 1  | 68 FL                 |                       |
| (y) Tripletail  | All Year   | 2  | 18 TL                 |                       |
| (z) Weakfish  | All Year   | 1  | 13 TL                 |                       |
| (aa) White marlin   | No Open Season has been established by the Board of Natural Resources. |  |                       |                       |
| (bb) American eel   | All Year   | 25                                       | 9 TL                  |                       |
| (cc) Hammerhead Sharks  | All Year   | 1 per person or boat                     | 78 FL                 |                       |
| (dd) Shortfin Mako Shark  | All Year   | 1 per person or boat                     | 83 FL                 |                       |

(4) **Restrictions on Sale.** It shall be unlawful for any person in this state to sell, purchase, or barter any of the following species or part thereof, except as otherwise specifically provided herein:

(a) No person operating as a dealer may buy or sell sharks, small shark composite species, hammerhead sharks, and shortfin mako sharks caught in state waters without first obtaining a federal Commercial Shark Dealer Permit and when state or federal quotas for species within those groups have been reached.

(b) Tarpon.

(c) No person may sell any fish managed under federal law and harvested from either Georgia waters or the South Atlantic Exclusive Economic Zone except when the catch of such fish is allowed by applicable federal law. This prohibition of sale does not apply to fish harvested, landed, and sold in compliance with applicable federal law and held in cold storage by a seafood dealer or processor. This prohibition also does not apply to a seafood dealer's purchase or sale of fish harvested from waters other than those of Georgia or the South Atlantic Exclusive Economic Zone, provided such fish is accompanied by documentation of legal harvest.

(d) Reserved

(e) Reserved

**(5) Possession and Landing Specifications.**

(a) All fish subject to restrictions specified in this Rule may be possessed in state waters or landed only with head and fins intact, except that when landed for commercial purposes, all sharks, small shark composite species, hammerhead sharks, and shortfin mako sharks may have the heads removed but fins and tail must remain naturally attached.

(b) It shall be unlawful to transfer at sea in State waters from a fishing vessel to any other vessel or person any fish caught which are subject to the restrictions specified in this Rule.

(c) Except as otherwise provided by law, it shall be unlawful to fish for sharks, small shark composite species, hammerhead sharks, or shortfin mako sharks for recreational purposes with any gear other than rod and reel or handline as defined in subparagraph (2)(f) above. Additionally, anglers must use non-offset, corrodible, non-stainless-steel circle hooks when fishing for sharks recreationally, except when fishing with flies or artificial lures.

(d) Except as otherwise provided by law, trawlers fishing for shrimp for human consumption pursuant to Code Section [27-4-133](#) shall be exempt from the creel and possession limits for spot and Atlantic croaker.

**AUTHORITY:** O.C.G.A. §§ [12-2-24](#), [27-1-4](#), [27-4-10](#).

**HISTORY:** Original Rule entitled "Saltwater Finfishing" adopted. F. Aug. 24, 1989; eff. Sept. 13, 1989.

**Amended:** F. July 30, 1991; eff. Aug. 19, 1991.

**Amended:** F. Feb. 26, 1992; eff. Mar. 17, 1992.

**Amended:** F. July 22, 1992; eff. Aug. 11, 1992.

**Amended:** F. July 26, 1993; eff. Aug. 15, 1993.

**Amended:** F. Nov. 3, 1995; eff. Nov. 23, 1995.

**Amended:** ER. 391-2-4-0.34-.04 adopted. F. and eff. Jan. 29, 1997, the date of adoption, to be in effect for 120 days or until the effective date of a permanent Rule covering the same subject matter is adopted, as specified by the Agency.

**Amended:** F. Apr. 23, 1997; eff. May 13, 1997.

**Amended:** F. Oct. 23, 1998; eff. Nov. 12, 1998.

**Amended:** F. Oct. 28, 1999; eff. Nov. 17, 1999.

**Amended:** F. Aug. 28, 2001; eff. Sept. 17, 2001.

**Amended:** F. Dec. 8, 2006; eff. Dec. 28, 2006.

**Amended:** Feb. 11, 2009; eff. Mar. 3, 2009.

**Amended:** F. Mar. 25, 2010; eff. Apr. 14, 2010.

**Amended:** F. Dec. 18, 2012; eff. Jan. 7, 2013.

**Amended:** F. Dec. 13, 2013; eff. Jan. 2, 2014.

**Amended:** F. Feb. 5, 2014; eff. Feb. 25, 2014.

**Amended:** F. Dec. 7, 2015; eff. Jan. 1, 2016, as specified by the Agency.

**Amended:** F. Feb. 7, 2018; eff. Mar. 1, 2018, as specified by the Agency.

**Amended:** F. Feb. 10, 2020; eff. Mar. 1, 2020.

### **391-2-4-.18 Shellfish sanitation; seed importation; water bottoms lease terms**

(1) **Purpose.** The purpose of this Rule is to implement the authority of the Board of Natural Resources to promulgate rules and regulations based on current, sound principles of wildlife research and management establishing commercial shellfish sanitation requirements, seed size and importation criteria, and water bottoms lease terms.

(2) **Adoption of National Shellfish Sanitation Program Model Ordinance.** The following publication is adopted by reference and is part of these Rules: The National Shellfish Sanitation Program ("NSSP") Model Ordinance entitled "Guide for the Control of Molluscan Shellfish Model Ordinance" ("Guide") covering the sanitation of harvesting, processing, and distribution of shellfish. Violations of the Guide are violations of these Rules, and the Department of Natural Resources is authorized to enforce any requirements set forth in the Guide.

(3) **Hatcheries and Nurseries.** All hatcheries and nurseries providing shellfish seed, whether in-state or out-of-state, must be certified by the department. Certification is based upon current, sound principles of wildlife research and management and history of shellfish disease in the vicinity of the hatchery or nursery facility.

(4) **Commercial shellfish seed size.** Clam seed shall not be greater than one-half inch and oyster seed shall not be greater than one inch.

(5) **Shellfish Seed Health Requirements, Importation.** For the purpose of possessing shellfish seed for mariculture in this state, any person permitted to conduct mariculture operations according to this section must adhere to the following:

(a) All shellfish seed used in mariculture must originate only from hatcheries or nurseries certified by the department; and

(b) Shellfish seed from out-of-state hatchery and nursery facilities must be accompanied by a Certificate of Health from a Department-approved pathologist certifying the shellfish seed as free from disease and pathogens and must include the following:

- (i) Location(s) where the shellfish seed was spawned and nursed;
  - (ii) Size of shellfish seed tested;
  - (iii) List of diseases and pathogens in the analysis as required by the department;
  - (iv) Shellfish species tested;
  - (v) An indication that the shellfish seed was tested within 30-days prior to entering this state unless waived by the Department; and
  - (vi) Copies of the Certificate of Health must be maintained by the hatchery and/or nursery and the master harvester for a period of not less than three years.
- (c) Visual inspection of out-of-state shellfish seed shipments prior to placement on a lease must be granted upon request by the Department. Imported seed may be rejected if there is non-conformance of shellfish seed size or comingling of species that is not listed on the bill of lading or invoice that accompanies such shipment.
- (6) Leasing of State-Owned Water Bottoms Terms, Siting, other Considerations.**
- (a) The term of a state-owned water bottoms lease shall not exceed ten years and is subject to such provisions, requirements and conditions as determined by the Department. Leases may be renewed for additional terms if the lessee is in compliance with the terms of the current lease.
  - (b) Subtidal water bottoms leases shall be sited in accordance with the following criteria:
    - (i) In Approved Shellfish Growing areas as determined by the department;
    - (ii) In areas with a minimum width of 200 feet at mean low water;
    - (iii) In areas with a minimum depth of not less than 6 feet at mean low water; and
    - (iv) Not on or over an existing shellfish resource, live bottom or saltmarsh.
  - (c) Any boundary of a subtidal water bottom lease shall not be within the following:
    - (i) 150 feet of a federal project, such as a federally maintained channel;
    - (ii) 50 feet of an existing commercial, community or private dock; and
    - (iii) 50 feet of a shoreline at mean low water.
  - (d) Subtidal water bottoms leases may only be located within or adjacent to certain resources if the Department determines, after consulting with the appropriate local, state or federal agencies with jurisdiction over the subject matter, that the lease is compatible with the following:
    - (i) Critical habitat for marine, threatened or endangered species;
    - (ii) Bait shrimping zones; and
    - (iii) Heritage Preserves as defined in O.C.G.A. Title 12.
  - (e) Before siting a subtidal water bottoms lease the Department shall evaluate such other considerations as it deems necessary, but shall include at a minimum the following:

(i) Areas with known pre-existing or historical commercial, recreational and private uses of the waterway such as commercial and recreational fishing, high boat traffic, riparian viewsheds, and research sites;

(ii) Areas where property owners may exercise riparian rights to construct docks or marinas; and

(iii) Areas of dynamic shorelines and shoaling.

**AUTHORITY:** O.C.G.A. §§ [27-1-4](#), [27-4-189](#), [27-4-195](#).

**HISTORY:** Original Rule entitled "Shellfish sanitation; seed importation; water bottoms lease terms" adopted. F. Feb. 17, 2020; eff. Mar. 1, 2020, as specified by the Agency.

# Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

## Chapter 391-3. ENVIRONMENTAL PROTECTION

### Subject 391-3-17. RADIOACTIVE MATERIALS

#### 391-3-17-.02 Licensing of Radioactive Material

##### (1) Purpose and Scope.

(a) This Rule, [391-3-17-.02](#), provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this Rule or as otherwise provided in this Chapter. However, nothing in this Rule shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.

(b) In addition to the requirements of this Rule, all licensees are subject to the requirements of Rules [.01](#), [.03](#), [.06](#), [.07](#), [.10](#), and [.11](#) of this Chapter. Licensees engaged in industrial radiographic operations are subject to the requirements of Rule [.04](#) of this Chapter. Licensees using radioactive material in the healing arts are also subject to the requirements of Rule [.05](#) of this Chapter. Licensees engaged in the extrusion, mining, storage, beneficiating, processing, use, transfer, or disposal of NORM in such a manner as to alter the chemical properties or physical state of the NORM or its potential exposure pathways to humans are also subject to the requirements of Rule [.08](#) of this Chapter. Licensees using irradiators whose dose rate exceeds 500 rads (5 Grays) per hour at one meter from the radioactive sealed sources are also subject to the requirements of Rule [.09](#) of this Chapter.

Note: All numbered and lettered references within this Rule refer to parts of this Rule, unless stated otherwise.

##### (2) Exemptions/Source Material.

(a) Any person is exempt from this Rule to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this Rule to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from this Rule to the extent that such person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in:

(i) Incandescent gas mantles,

(ii) Vacuum tubes,

(iii) Welding rods,

(iv) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium,

(vi) Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

(vii) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

2. Source material contained in the following products:

(i) Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material,

(ii) Glassware containing not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

(iii) Glassware containing not more than 2 percent by weight source material, or for glassware manufactured before August 27, 2013, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction, or

(iv) Piezoelectric ceramic containing not more than two percent by weight source material;

3. Photographic film, negatives, and prints containing uranium or thorium;

4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(i) Each such counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",

(ii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED", and

(iii) This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

Note: The requirements specified in (2)(c)5.(i) and (ii) need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend: "CAUTION - RADIOACTIVE MATERIAL - URANIUM".

6. Natural or depleted uranium metal used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend: "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and the uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm);

7. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that this exemption contained in this subparagraph (c) does not authorize either:

(i) The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(ii) The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, in spectacles, or in eyepieces in binoculars or other optical instruments;

8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(i) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

(ii) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

10. No person may initially transfer for sale or distribution a product containing source material to persons exempt under this subparagraph (c), or equivalent regulations of an Agreement State or the U.S. Nuclear Regulatory Commission, unless authorized by a license issued under [10 CFR 40.52](#) to initially transfer such products for sale or distribution.

(i) Persons initially distributing source material in products covered by the exemptions in this subparagraph (c) before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

(ii) Persons authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under [10 CFR 40.52](#) for distribution only and are exempt from the requirements of [10 CFR 19 and 20](#) and [10 CFR 40.32\(b\) and \(c\)](#).

(d) The exemptions in paragraph (2)(c) do not authorize the manufacture of any of the products described.

### **(3) Exemptions/Radioactive Material Other Than Source Material.**

#### **(a) Exempt Concentrations.**

1. Except as provided in (3)(a)3. and 4., any person is exempt from this Chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires products containing radioactive material in concentrations not in excess of those listed in (21)(a), Schedule A.

2. This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

3. A manufacturer, processor, or producer of a product or material is exempt from the requirements of this Rule to the extent that this person transfers products containing radioactive material in concentrations not in excess of those listed in (21)(a) Schedule A and introduced into the product or material by a licensee holding a specific license issued by the Director expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under (3)(a). or equivalent Regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State, except in accordance with a specific license issued pursuant to [10 CFR 32.11](#).

#### **(b) Exempt Quantities.**

1. Except as provided in (3)(b)3. through 5., any person is exempt from this Chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in (21)(b), Schedule B.
2. Any person, who possesses radioactive material received or acquired before September 25, 1971, under the general license then provided in [10 CFR 31.4](#), or similar general license of an Agreement State, is exempt from the requirements of this Chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.
3. Paragraph (3)(b) does not authorize the production, packaging, repackaging, or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in (21)(b), Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under (3)(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or a Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section [32.18](#) of 10 CFR, Part 32, or by the Director pursuant to (11)(b) which license states that the radioactive material may be transferred by the licensee to persons exempt under (3)(b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.
5. No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in (21)(b), Schedule B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by this Chapter.

(c) Exempt Items.

1. Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

Note: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C., 20555.

(i) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rates:

(I) 25 millicuries (925 MBq) of tritium per timepiece.

(II) 5 millicuries (185 MBq) of tritium per hand.

(III) 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).

(IV) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

(V) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.

(VI) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(VII) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

I. For wrist watches, 0.1 millirad (1  $\mu$ Gy) per hour at ten centimeters from any surface.

II. For pocket watches, 0.1 millirad (1  $\mu$ Gy) per hour at one centimeter from any surface.

III. For any other timepiece, 0.2 millirad (2  $\mu$ Gy) per hour at ten centimeters from any surface.

(VIII) One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(ii) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500  $\mu$ Ci) of polonium-210 per device.

(iii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500  $\mu$ Ci) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iv) Such devices authorized before October 23, 2012, for use under the general license then provided in Section [31.3](#) of 10 CFR, Part 31 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Director.

(v) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

(vi) [Reserved]

(vii) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

(viii) [Reserved]

(ix) Ionization chamber smoke detectors containing not more than 1 microcurie ( $\mu$ Ci) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(x) Electron tubes, provided that the levels of radiation from each electron tube containing radioactive material will not exceed one millirad (10  $\mu$ Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. Provided also, that each tube does not contain more than one of the following specified quantities of radioactive material:

(I) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or ten millicuries (370 MBq) of tritium per any other electron tube.

(II) 1 microcurie (37 kBq) of cobalt-60.

(III) 5 microcuries (185 kBq) of nickel-63.

(IV) 30 microcuries (1.11 MBq) of krypton-85.

(V) 5 microcuries (185 kBq) of cesium-137.

(VI) 30 microcuries (1.11 MBq) of promethium-147.

NOTE: For the purpose of .02(3)(c)1.(x), "Electron tubes" includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(xi) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(I) Each source contains no more than one exempt quantity set forth in (21)(b), Schedule B;

(II) Each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities specified in (21)(b), Schedule B, provided that the sum of such fractions shall not exceed unity; and

(III) For purposes of .02(3)(c)1.(xi), 0.05 microcurie (1.85 kBq) of americium-241 is considered an exempt quantity under (21)(b), Schedule B.

(xii) [Reserved]

(xiii) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in 3(c)1., or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license with the U.S. Nuclear Regulatory Commission pursuant to Section [32.14](#) of 10 CFR, Part 32, which license states that the product may be distributed by the licensee to persons exempt under (3)(c)1., or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

## 2. Self-Luminous Products Containing Radioactive Material.

(i) Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the requirements for a license set forth in this Chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section [32.22](#) of 10 CFR, Part 32, which license authorizes the initial transfer of the product to persons who are exempt from regulatory requirements. This exemption does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from this Chapter to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 that were acquired prior to July 12, 1982.

(iii) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph .02(3)(c)2.(i) should apply for a license with the U.S. Nuclear Regulatory Commission pursuant to Section [32.22](#) of 10 CFR Part 32 and apply to the U.S. Nuclear Regulatory Commission for a certificate of registration in accordance with Section [32.210](#) of 10 CFR Part 32.

## 3. Gas and Aerosol Detectors Containing Radioactive Material.

(i) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in this Chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property provided that detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section [32.26](#) of 10 CFR, Part 32. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in

accordance with a specific license issued by a State under comparable provisions to Section [32.26](#) of 10 CFR, Part 32 authorizing distribution to persons exempt from regulatory requirements.

(ii) Gas and aerosol detectors containing naturally-occurring and accelerator-produced radioactive material (NARM) previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under (3)(c)3.(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of [10 CFR 32.26](#).

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under (3)(c)3.(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of [10 CFR 32.26](#).

(iv) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under .02(3)(c)3.(i) should apply for a license with the U.S. Nuclear Regulatory Commission pursuant to Section [32.26](#) of 10 CFR Part 32 and apply to the U.S. Nuclear Regulatory Commission for a certificate of registration in accordance with Section [32.210](#) of 10 CFR, Part 32.

4. Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

(i) Except as provided in [.02\(3\)\(c\)4.\(ii\)](#) and [.02\(3\)\(c\)4.\(iii\)](#), any person is exempt from the requirements for a license set forth in O.C.G.A. Section [31-13-5\(a\)\(9\)](#) (Georgia Radiation Control Act) and from the regulations in this Chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing one  $\mu\text{Ci}$  (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(ii) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Rule [.02](#) and Rule [.05](#) of this chapter.

(iii) Any person who desires to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to Rule [.02](#) of this chapter.

(iv) Nothing in [.02\(3\)\(c\)4.](#) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

5. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in this Chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under Section [32.30](#) of 10 CFR Part 32, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

6. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under [.02\(3\)\(c\)5.](#) should apply for a license to the U.S. Nuclear Regulatory Commission pursuant to Section [32.30](#) of 10 CFR Part 32 and to the U.S. Nuclear Regulatory Commission for a certificate of registration in accordance with [§ 32.210](#) of 10 CFR, Part 32.

(4) **Types of Licenses.** Licenses for radioactive materials are of two types: general and specific.

(a) General licenses provided in this Rule are effective without the filing of applications with the Division or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Division may be required by the particular general license. The general licensee is subject to all other applicable portions of this Chapter and any limitations of the general license.

(b) Specific licenses require the submission of an application to the Division and the issuance of a licensing document by the Director to a named person. The licensee is subject to all applicable portions of this Chapter as well as any limitations specified in the licensing document.

**(5) General Licenses - Source Material.**

(a) A general license is hereby issued authorizing persons to hold bare title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

(b) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

1. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this subparagraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Nuclear Regulatory Commission takes final action on a pending application submitted on or August 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Nuclear Regulatory Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

2. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this subparagraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this subparagraph unless it is accounted for under the limits of subparagraph (b)(1) of this section; or

3. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this subparagraph; or

4. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this subparagraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(c) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in subparagraph (b) of this section.

1. Is prohibited from administering source material, or the radiation there from, either externally or internally, to human beings except as may be authorized by the NRC in a specific license.

2. Shall not abandon such source material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the

provisions of this subparagraph (c) is exempt from the requirements to obtain a license under paragraph (5) to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under [391-3-17-.02\(7\)](#) through [391-3-17-.02\(13\)](#); or

(ii) In accordance with [391-3-17-.03\(13\)](#) of this Chapter.

3. Is subject to the provisions of [391-3-17-.03\(13\)](#) of this Chapter.

4. Is subject to the provisions in [391-3-17-.01\(4\), \(5\), \(6\) and \(8\)](#), [391-3-17-.02\(13\), \(18\) and \(19\)](#), and [391-3-17-.03\(14\) and \(15\)](#).

5. Shall not export such source material except in accordance with [10 CFR Part 110](#).

(d) Depleted Uranium in Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of (5)(d)2., 3., 4., and 5., depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in (5)(d)1. applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by (5)(d)1. shall:

(i) File Division form "Registration Certificate - Use of Depleted Uranium Under General License" with the Division. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on the form the following information and such other information as may be required by that form:

(I) Name and address of the registrant;

(II) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in (5)(d)1. and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(III) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in (5)(d)3.(i)(II); and

(ii) Report in writing to the Division any changes in information furnished by him in Division form "Registration Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by (5)(d)1:

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) Shall not abandon such depleted uranium;

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of (19). In the case where the transferee receives the depleted uranium pursuant to the general license established by (5)(d)1., the transferor shall furnish the transferee a copy of this Regulation and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License". In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to (5)(d)1., the transferor shall furnish the transferee a copy of this Regulation and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this Regulation;

(iv) Shall report in writing to the Division the name and address of the person receiving the depleted uranium pursuant to such transfer within 30 days of any transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by (5)(d)1. is exempt from the requirements of Rule [.03](#) and Rule [.07](#) of this Chapter with respect to the depleted uranium covered by that general license.

(e) Any person who receives, possesses, uses, or transfers source material in accordance with subparagraph (b) of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Division about such contamination and may consult with the Division as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in [10 CFR 20.1402](#).

(f) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in subparagraph (b) of this section is exempt from the provisions of [391-3-17-.03](#) and [391-3-17-.07](#) to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of [391-3-17-.03\(7\)\(b\)](#) and [391-3-17-.03\(13\)\(a\)](#) to the extent necessary to meet the provisions of subparagraphs (c)(2) and (e) of this section. However, this exemption does not apply to any person who also holds a specific license issued under this Chapter.

(g) No person may initially transfer or distribute source material to persons generally licensed under subparagraph (b) of this section, or equivalent regulations of an Agreement State or NRC, unless authorized by a specific license issued in accordance with [391-3-17-.02\(5\)\(h\)](#), [10 CFR 40.54](#), or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

(h) An application for a specific license to initially transfer source material for use under [391-3-17-.02](#) will be approved if:

1. The applicant satisfies the general requirements specified in this Chapter; and
2. The applicant submits adequate information on, and the Division approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(i) Each person licensed under [391-3-17-.02](#) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(j) Each person licensed under [391-3-17-.02](#) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(k) Each person licensed under [391-3-17-.02](#) shall report transfers as follows:

1. File a report with the Division. The report shall include the following information:

- (i) The name, address, and license number of the person who transferred the source material;
- (ii) For each general licensee under [391-3-17-.02](#), [10 CFR 40.22](#) and equivalent Agreement State regulations or provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and
- (iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

2. File a report with each responsible Agreement State agency or NRC that identifies all persons, operating under provisions equivalent to this Chapter, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State or NRC being reported to:

- (i) The name, address, and license number of the person who transferred the source material; and
- (ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.
- (iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or NRC.

3. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under [10 CFR Part 40.22](#) or equivalent Agreement State or NRC provisions during the current period, a report shall be submitted indicating so. If no transfers have been made to general licensees in a particular Agreement State or falling under the jurisdiction of the NRC, during the reporting period, this information shall be reported to the NRC or responsible Agreement State agency upon request of the agency or NRC.

(l) Each person licensed under [391-3-17-.02](#) shall maintain all information that supports the reports required by this subparagraph concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Division, Commission or to an Agreement State agency.

(m) Each person licensed under [391-3-17-.02\(5\)\(h\)](#) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under [391-3-17-.02\(5\)\(b\)](#). This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

1. A copy of [391-3-17-.02\(5\)\(b\)](#) and [.02\(19\)](#) or relevant equivalent regulations of the NRC or an Agreement State.
2. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

**(6) General Licenses - Radioactive Materials Other Than Source Material.** Each general license issued under (6) has its own specific conditions and requirements.

(a) **Ownership of Radioactive Material.** A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Rule, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

(b) [Reserved]

(c) Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionizing Atmosphere.

1. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use, or transfer, in accordance with the provisions of (6)(c)2., 3., and 4., radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

2. The general license in (6)(c)1. applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained:

(i) in a specific license issued by the Director pursuant to (11)(d); or

(ii) in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

The devices must have been received from one of the specific licensees described in (i) or (ii) above or through a transfer made under (6)(c)3.(viii).

Note: Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section [179.21](#) of the Code of Federal Regulations, Title 21.

3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (6)(c)1.:

(i) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on/off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however,

(I) Devices containing only krypton need not be tested for leakage of radioactive material, and

(II) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta-and/or gamma-emitting material or ten microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) Shall assure that the tests required by (6)(c)3.(ii) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(I) In accordance with the instructions provided by the labels, or

(II) By a person holding an applicable specific license from the Director, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of (6)(c)3.(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding, or containment. Records of tests for leakage of radioactive material required by (6)(c)3.(ii) shall be maintained for three years after the next required leak test is performed. Records of tests of the on/off mechanism

and indicator required by (6)(c)3.(ii) shall be maintained for three years after the next required test of the on/off mechanism and indicator is performed. Records which are required by (6)(c)3.(iii) shall be maintained for three years. In case of transfer or disposal, records required by this paragraph (iv) shall be maintained for three years after the transfer or disposal.

(v) Shall, upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, immediately suspend operation of the device. The device may not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Director, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Division. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie (185 Bq) or more of removable radioactive material, or failure or damage to a source likely to result in contamination of the premises or environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Division within 30 days. Under these circumstances, the criteria set out in Rule [.03\(7\)\(b\)](#) "Radiological requirements for unrestricted use" may be applicable, as determined by the Division on a case-by-case basis;

(vi) Shall not abandon the device containing radioactive material;

(vii) (I) Shall transfer or dispose of the device containing radioactive material only by export as provided in (6)(c)3.(xiv), by transfer to another general licensee as specified in (6)(c)3.(viii) or equivalent regulations of the NRC or another Agreement State, by transfer to a specific licensee of the Director, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State whose specific license authorizes him to receive the device or authorizes him to collect waste, or as otherwise approved under (6)(c)3.(vii)(III).

(II) Within 30 days after transfer of a device to a specific licensee or export, the licensee shall furnish to the Division a report containing identification of the device by manufacturer's (or initial transferor's) name, model number, serial number, the name and address and license number (license number not applicable if exported) of the person receiving the device and the date of transfer;

(III) If transfer is to any other licensee not identified in (vii)(I), the licensee shall obtain written approval from the Division before transferring the device to any other person; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

I. Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

II. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by Rule [.02\(6\)\(c\)3.\(i\)](#) so that the device is labeled in compliance with Rule [.03\(12\)\(d\)](#); however the manufacturer, model number, and serial number must be retained;

III. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

IV. Reports the transfer under Rule [.02\(6\)\(c\)3.\(vii\)](#)

(viii) Shall transfer the device to another general licensee only:

(I) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this Regulation and any safety documents identified in the label on the device. Within 30 days of the transfer, report to the Division the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the name and mailing address for place of use of the transferee, and the name, title and telephone number of a person identified by the transferee as the individual responsible for having knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(II) Where the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

(ix) Shall comply with the provisions of Rule [.03\(15\)](#) of this Chapter for reporting radiation incidents, or the theft or loss of licensed material, but shall be exempt from the other requirements contained in Rules [.03](#) and [.07](#) of this Chapter;

(x) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(xi) (I) Shall register, in accordance with paragraphs (6)(c)3.(xi)(II) and (III), devices containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium 226, or 1 mCi (37 MBq) of americium-241 or any other transuranic [i.e., element with atomic number greater than uranium (92)], based on the activity indicated on the label. Each address for a location of use, as described under paragraph 3.(xi)(III)IV. of this section, represents a separate general licensee and requires a separate registration.

(II) If in possession of a device meeting the criteria of paragraph (6)(c)3.(xi)(I), shall register these devices annually with the Division. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Division. The registration information must be submitted to the Division within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of (6)(c)3.(xi)(I) is subject to the bankruptcy notification requirement in (13)(e) of this rule.

(III) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Division;

I. Name and mailing address of the general licensee.

II. Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

III. Name, title, and telephone number of the responsible person designated as a representative of the general licensee under (6)(c)3.(x).

IV. Address or location at which the device(s) are used and/or stored.

V. Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

VI. Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(IV) Persons generally licensed by the NRC, an Agreement State, or Licensing State are not eligible for reciprocity.

(xii) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Division within 30 days of the effective date of the change;

(xiii) May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by (6)(c)3.(ii) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the

shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(xiv) Shall not export the device containing byproduct material except in accordance with the requirements of [10 CFR Part 110](#).

(xv) Shall respond to written requests from the Program to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Program a written justification for the request.

4. The general license in (6)(c)1. does not authorize the manufacture or import of devices containing radioactive material.

5. The general license provided in (6)(c)1. is subject to the provisions of (13), (18), and (19) of this rule, of paragraphs (4), (5), (6), (7), (8), (9) and (10) of Rule [.01](#), and of Rule [.06](#) of this Chapter.

(d) Luminous Safety Devices for Aircraft.

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) Each device contains not more than ten Curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(ii) Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Director or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section [32.53](#) of 10 CFR, Part 32, of the regulations of the U.S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in (6)(d) are exempt from the requirements of Rules [.03](#) and [.07](#) of this Chapter, except that they shall comply with the provisions of Rule [.03\(15\)](#) of this Chapter.

3. This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

4. This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium-147 contained in instrument dials.

5. This general license is subject to the provisions of paragraphs (13), (18), and (19) of this Rule, of paragraphs (4), (5), (6), (7), (8), (9) and (10) of Rule [.01](#), and of Rule [.06](#) of this Chapter.

(e) Ice-Detection Devices.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice-detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Director or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section [32.61](#) of 10 CFR, Part 32, of the regulations of the U.S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice-detection devices pursuant to the general license in (6)(e)1.:

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license or equivalent licensing document from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of Rule [.03\(13\)](#) of this Chapter;

(ii) Shall assure that all labels affixed to the device at the time of receipt and which bear a statement that prohibits removal of the labels are maintained thereon; and

(iii) Are exempt from the requirements of Rules [.03](#) and [.07](#) of this Chapter except that such persons shall comply with the provisions of Rule [.03\(13\)](#) and [\(15\)](#) of this Chapter.

3. This general license does not authorize the manufacture, assembly, disassembly, or repair of strontium-90 in ice-detection devices.

4. This general license is subject to the provisions of paragraphs (13), (18), and (19) of this Rule, of paragraphs (4), (5), (6), (7), (8), (9) and (10) of Rule [.01](#), and of Rule [.06](#) of this Chapter.

(f) Calibration and Reference Sources.

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of (6)(f)4. and 5., americium-241 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the Director which authorizes him to receive, possess, use, and transfer radioactive material; and

(ii) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of (6)(f)4. and 5. to any person who holds a specific license issued by the Director which authorizes him to receive, possess, use, and transfer radioactive material.

3. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of (6)(f)4. and 5. to any person who holds a specific license issued by the Director which authorizes him to receive, possess, use, and transfer radioactive material.

4. The general licenses in (6)(f)1., 2., and 3. apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section [32.57](#) of 10 CFR, Part 32, or Section [70.39](#) of 10 CFR, Part 70, or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Director, any Agreement State, or Licensing State pursuant to licensing requirements equivalent to those contained in Section [32.57](#) of 10 CFR, Part 32, or Section [70.39](#) of 10 CFR, Part 70, of the regulations of the U.S. Nuclear Regulatory Commission.

5. The general licenses provided in (6)(f)1., 2., and 3. are subject to the provisions of paragraphs (13), (18), and (19) of this Rule, of paragraphs (4), (5), (6), (7), (8), (9) and (10) of Rule [.01](#), and of Rules [.03](#), [.06](#), and [.07](#) of this Chapter. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) of americium-241, five microcuries (185 kBq) of plutonium, or five microcuries (185 kBq) of radium-226 in such sources;

(ii) Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label that includes one of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, as appropriate:

(I) The receipt, possession, use, and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL -

THIS SOURCE CONTAINS (AMERICIUM-241)\*

(PLUTONIUM)\*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

\_\_\_\_\_  
(NAME OF MANUFACTURER OR IMPORTER)

\*Note: Showing only the name of the appropriate material, i.e., either plutonium or americium.

(II) The receipt, possession, use, and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL -

THIS SOURCE CONTAINS RADIUM-226.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

\_\_\_\_\_  
(NAME OF MANUFACTURER OR IMPORTER)

(iii) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Director, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive the source;

(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

6. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(g) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.

Note: The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specified diagnostic drugs in interstate commerce.

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following radioactive material, in accordance with the provisions of (6)(g) 2., 3., 4., 5., and 6., the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

- (i) Iodine-125, in units not exceeding ten microcuries (370 kBq) each.
- (ii) Iodine-131, in units not exceeding ten microcuries (370 kBq) each.
- (iii) Carbon-14, in units not exceeding ten microcuries (370 kBq) each.
- (iv) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
- (v) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
- (vi) Cobalt-57, in units not exceeding ten microcuries (370 kBq) each.
- (vii) Selenium-75, in units not exceeding ten microcuries (370 kBq) each.
- (viii) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by (6)(g)1. until he has filed Division form, "Certificate - In-Vitro Testing with Radioactive Material Under General License" with the Division and received from the Division a validated copy of this form with certification number assigned or until he has been authorized pursuant to (9)(e)3. to use radioactive material under the general license in (6)(g). The physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital shall furnish on the form the following information and such other information as may be required by that form:

(i) Name and address of the physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital;

(ii) The location of use; and

(iii) A statement that the physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in (6)(g)1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by (6)(g)1. shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in (6)(g)1., at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing the equivalent amount of radiation protection.

(iii) The general licensee shall use the radioactive material only as authorized by (6)(g)1.

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Director, the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in (6)(g)1.(viii) as required by Rule [03\(13\)](#) of this Chapter.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to (6)(g)1.:

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to (11)(g) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under (6)(g) or its equivalent, and

(ii) Unless one of the following statements, as appropriate, or a statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(I) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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(NAME OF MANUFACTURER)

(II) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

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(NAME OF MANUFACTURER)

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital possessing or using radioactive material under the general license of (6)(g)1. shall report in writing to the Division any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License". The report shall be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of (6)(g)1. is exempt from the requirements of Rules [.03](#) and [.07](#) of this Chapter with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in (6)(g)1.(viii) shall comply with the provisions of (13) and (15) of Rule [.03](#) of this Chapter.

**(7) Filing Application for Specific Licenses.**

(a) Applications for specific licenses shall be filed on forms supplied by the Georgia Department of Natural Resources, Environmental Protection Division, Radioactive Materials Program, 4244 International Parkway, Suite 120, Atlanta, Georgia, 30354, or current mailing address. The application shall set forth all applicable information called for by the form.

(b) The Division may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Director to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Division, provided that such references are clear and specific by page, paragraph, and date.

(f) Applications and documents submitted to the Division may be made available for public inspection except those documents described in Rule [.01\(5\)\(c\)](#) which may be withheld from public inspection or discovery.

(g) The Division may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location where radioactive materials would be possessed, or used, and by discussing details of proposed possession or use of the radioactive materials with the applicant or the applicant's designated representatives.

(h) Emergency Plan for Large Quantity Users.

1. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities specified in (21)(e), Schedule E, must contain either:

(i) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed one rem (.01 Sv) effective dose equivalent or five rems (.05 Sv) to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

2. One or more of the following factors may be used to support an evaluation submitted under (7)(h)1.(i):

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) The release fraction in the respirable size range would be lower than the release fraction shown in (21)(e), Schedule E, due to the chemical or physical form of the material;

(iv) The solubility of the radioactive material would reduce the dose received;

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in (21)(e), Schedule E;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in (21)(e), Schedule E; or

(vii) Other factors appropriate for the specific facility.

3. An emergency plan for responding to a release of radioactive material submitted under (7)(h)1.(ii) must include the following information:

(i) Facility description - a brief description of the licensee's facility and the area near the site.

(ii) Types of accidents - an identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents - a classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents - identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences - a brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment.

(vi) Assessment of releases - a brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities - a brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Division; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination - a commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established to prevent spreading of contamination during recovery activities. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Division immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

Note: This Chapter does not supersede or release licensees from complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L-99-499 or other State or Federal reporting requirements.

(ix) Information to be communicated - a brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Division.

(x) Training - a brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instruction and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown - a brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises - provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site, and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and the overall effectiveness of the response. These exercises must be documented and deficiencies found by the critiques must be corrected.

(xiii) Hazardous chemicals - a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

4. The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Division. The licensee shall provide any comments received within the 60 days to the Division with the emergency plan.

(i) Except as provided in paragraphs 2., 3. and 4. of this section, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must:

1. Identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission, an Agreement State, or for a source or a device containing radium-226 or accelerator produced radioactive material with a State under provisions comparable to Section [32.210](#) of 10 CFR Part 32.

2. For sources or devices manufactured before October 23, 2012, that are not registered with the Commission under Section [32.210](#) of 10 CFR, Part 32 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in Section [32.210\(c\)](#) of 10 CFR, Part 32, the application must include:

(i) All available information identified in Section [32.210\(c\)](#) of 10 CFR, Part 32 concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

3. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with Section [32.210\(g\)\(1\)](#) of 10 CFR, Part 32, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

4. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Rule [.05](#) or equivalent Nuclear Regulatory Commission or Agreement State requirements shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under Rule [.02](#), Nuclear Regulatory Commission or of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in [.02\(11\)\(i\)2.](#) of this Rule.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in [.02\(11\)\(i\)5.](#) of this Rule.

4. Information identified in Rule [.02\(11\)\(i\)3.](#) of this Rule on the PET drugs to be noncommercially transferred to members of its consortium.

**(8) General Requirements for the Issuance of Specific Licenses.** A license application will be approved if the Division determines the following:

(a) That the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this Chapter in such a manner as to minimize danger to public health and safety or property;

(b) That the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(c) That the issuance of the license will not be inimical to the health and safety of the public; and

(d) That the applicant satisfies any applicable special requirements in (9), (10), and (11).

(e) Bonding Requirements.

1. Pursuant to Georgia Laws 1979, pp. 1059, 1060, a specific license will be issued to a Major Processor as defined in Rule [.01\(2\)](#) of this Chapter only if the applicant has posted a surety bond with, and made payable to, the Director, Environmental Protection Division, Department of Natural Resources, to ensure the protection of the public health and safety in the event of abandonment, insolvency, or other inability of the licensee to meet the requirements of the Act and this Chapter.

(i) The bond provided shall be not less than \$100,000.00, nor more than \$5,000,000.00.

(ii) The exact amount of the bond shall be determined by the Director, Environmental Protection Division, and shall be based on the probable extent of contamination, the amount of possible property damage, the costs of removal and disposal of sources of radiation used by the licensee, and the costs of reclamation of the property in the event of abandonment, insolvency, or other inability of the licensee to meet the requirements of the Act and this Chapter, including performing such services to the satisfaction of the Division.

2. Persons licensed at the time the bonding requirements of this Chapter became effective, and upon notice by the Division, must, within a period of 90 days following such notice, provide the bond required by (8)(e)1. as a condition for continuation of the license.

(f) Environmental Report, Commencement of Construction. In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Division determines will significantly affect the quality of the environment, commencement of construction of the plant or facility in which the activity will be conducted shall not begin until the Director has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(g) Financial assurance and record-keeping for decommissioning.

1. The following are required to furnish financial assurance and record-keeping for decommissioning:

(i) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding  $10^5$  times the applicable quantities set forth in Schedule F shall submit a decommissioning funding plan as described in subparagraphs (8)(g)5 and (8)(g)6. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if  $R$  divided by  $10^5$  is greater than 1 (unity Rule), where  $R$  is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Schedule F.

(ii) Each applicant for a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding  $10^{12}$  times the applicable quantities set forth in Schedule F shall submit a decommissioning funding plan as described in subparagraphs (8)(g)5 and (8)(g)6. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if  $R$  divided by  $10^{12}$  is greater than 1 (unity Rule), where  $R$  is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Schedule F.

2. Each applicant for a specific license authorizing the possession and use of radioactive material of half-life greater than 120 days and in quantities specified in subparagraphs (8)(g)4. shall either:

(i) Submit a decommissioning funding plan as described in subparagraphs (8)(g)5 and (8)(g)6.; or

(ii) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by (8)(g)4. using one of the methods described in (8)(g)7. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of (8)(g)7. is to be submitted to the Division. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements (8)(g)7. must be submitted to the Division before the receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Division, as part of the certification a signed original of the financial instrument obtained to satisfy the requirements of (8)(g)7.

3. (i) Each holder of a specific license issued on or after January 1, 1993, which is of a type described in (8)(g)1. or 2. shall provide financial assurance for decommissioning in accordance with the criteria set forth in this Rule.

(ii) Each holder of a specific license issued before January 1, 1993, which is of a type described in (8)(g)1. shall submit, on or before January 1, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this Rule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(iii) Each holder of a specific license issued before January 1, 1993, and of a type described in (8)(g)2. shall submit, on or before January 1, 1993, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this [.02\(8\)\(g\)](#).

(iv) Waste collectors and waste processors shall provide financial assurance in an amount based on a decommissioning funding plan as described in subparagraphs [.02\(8\)\(g\)5](#) and (8)(g)6. The decommissioning funding plan must also include the cost of disposal of the maximum amount (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination requirements in [.02\(18\)](#).

4. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than  $10^4$  but less than or equal to  $10^5$  times the applicable quantities of Schedule F in unsealed form. (For a combination of isotopes, if R, as defined in (8)(g), divided by  $10^4$  is greater than 1 but R divided by  $10^5$  is less than or equal to 1): \$1,125,000

Greater than  $10^3$  but less than or equal to  $10^4$  times the applicable quantities of Schedule F in unsealed form. (For a combination of isotopes, if R, as defined in (8)(g), divided by  $10^3$  is greater than 1 but R divided by  $10^4$  is less than or equal to 1): \$225,000

Greater than  $10^{10}$  times the applicable quantities of Schedule F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in (8)(g), divided by  $10^{10}$  is greater than 1): \$113,000

5. Each decommissioning funding plan must be submitted for review and approval and must contain

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(I) The cost of an independent contractor to perform all decommissioning activities;

(II) The cost of meeting the [.03\(7\)\(b\)](#) criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of [.03\(7\)\(c\)](#), the cost estimate may be based on meeting the [.03\(7\)\(c\)](#) criteria;

(III) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(IV) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from subparagraph 7 of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of subparagraph 7 of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

6. At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

7. Financial assurance for decommissioning must be provided by one or more of the following methods:

(i) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(ii) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in (21)(d) Schedule D. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a

guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in (21)(g) Schedule G. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in (21)(d) Schedule D. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in (21)(h) Schedule H. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(I) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically, unless 90 days or more prior to the renewal date the issuer notifies the Division, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Division within 30 days after receipt of notification of cancellation.

(II) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Division. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(III) The surety method or insurance must remain in effect until the Director has terminated the license.

(iii) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in (8)(g)2.

(iv) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in (8)(g)4., and indicating that funds for decommissioning will be obtained when necessary.

8. Each person licensed under this Chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use by the Division. Before licensed activities are transferred or assigned in accordance with [.02\(13\)\(b\)](#), licensees shall transfer all records described in (7)(i) through (iv) to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of relevant information to the decommissioning of a facility are kept for other purposes, references to these records and their locations may be used. Information the Division considers important to decommissioning consists of:

(i) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(ii) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(iii) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, or depleted uranium used only for shielding or as penetrators in unused munitions, a list contained in a single document and updated every two years, of the following:

(I) All areas designated and formerly designated as restricted areas as defined under Rule [391-3-17-.01\(2\)](#);

(II) All areas outside of restricted areas that require documentation under (8)(g)8.(i);

(III) All areas outside of restricted areas where current and previous wastes have been buried as documented under Rule [.03\(14\)\(i\)](#) of this Chapter; and

(IV) All areas outside of restricted areas that contain materials such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under Rule [.03\(13\)\(b\)](#) of this Chapter.

(iv) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

9. Teletherapy licensees are exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than  $10^{10}$  times the applicable quantities of Schedule F of this rule, for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

(h) Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

1. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Director notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(i) Limit actions involving radioactive material to those related to decommissioning; and

(ii) Continue to control entry to restricted areas until they are suitable for release in accordance with Division requirements.

2. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the Division in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Division requirements, or submit within 12 months of notification a decommissioning plan, if required by (8)(h)5.(i), and begin decommissioning upon approval of that plan if:

(i) The license has expired pursuant to (14) or (18)(c); or

(ii) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Division requirements; or

(iii) No principal activities under the license have been conducted for a period of 24 months; or

(iv) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Division requirements.

3. Coincident with the notification required by (8)(h)2., the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to (8)(g) in conjunction with a license issuance or renewal

or as required by this section. The amount of the financial assurance must be increased or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to (8)(h)5.(iv)(V).

(i) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective.

(ii) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Director.

4. The Division may grant a request to extend the time periods in (8)(h)2. if the Division determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to (8)(h)2. The schedule for decommissioning set forth in (8)(h)2. may not commence until the Director has made a determination on the request.

5. (i) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Division and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(I) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(II) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(III) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation or;

(IV) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(ii) The Division may approve an alternate schedule for submittal of a decommissioning plan required pursuant to (8)(h)2. if the Division determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(iii) Procedures such as those listed in (8)(h)5.(i) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(iv) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(I) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(II) A description of planned decommissioning activities;

(III) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(IV) A description of the planned final radiation survey; and

(V) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(VI) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in (8)(h)7.

(v) The proposed decommissioning plan will be approved by the Division if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

6. (i) Except as provided in (8)(h)7., licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practical but no later than 24 months following the initiation of decommissioning.

(ii) Except as provided in (8)(h)7. when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

7. The Division may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Division determines that the alternative is warranted by consideration for the following:

(i) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(ii) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(iii) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(iv) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(v) Other site-specific factors which the Division may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

8. As the final step in decommissioning, the licensee shall follow the requirements of Rule [.02\(18\)\(d\)](#).

**(9) Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.**

(a) Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in (8), a specific license for the use of sealed sources in industrial radiography will be issued if the licensee meets all of the requirements of Rule [.04](#) of this Chapter.

(b) Human Use of Radioactive Materials in Institutions. In addition to the requirements set forth in (8), a specific license for the human use of radioactive material in an institution will be issued only if the licensee also meets all of the requirements of Rule [.05](#) of this Chapter.

(c) Specific Licenses to Individual Physicians for Human Use of Radioactive Material.

1. An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:

(i) The applicant satisfies the general requirements specified in (8), and all of the requirements of Rule [.05](#) of this Chapter;

(ii) The application is for use in the applicant's practice in an office outside a medical institution;

(iii) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(iv) The applicant has extensive experience in the proposed use, the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.

2. The Director will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

(i) The use of radioactive material is limited to:

(I) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(II) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(III) The performance of in vitro diagnostic studies; or

(IV) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient.); and

(iii) The medical institution does not hold a radioactive material license under (9)(b).

(d) Human Use of Sealed Sources Containing Radioactive Material. In addition to the requirements set forth in (8), a specific license for the human use of sealed sources containing radioactive material will be issued only if the applicant, or, if the application is made by an institution, the individual user is a physician and either:

1. Has specialized training in the therapeutic use of the sealed source considered (e.g., teletherapy unit, beta applicator), or has experience equivalent to such training; or

2. Has specialized training in the diagnostic use of the sealed source considered (e.g., bone mineral analyzer) or has experience equivalent to such training.

(e) Specific Licenses for Certain Medical Uses of Radioactive Material.

1. Subject to the provisions of (9)(e)2. and 3., an application for a specific license pursuant to (9)(b), (c), or (d), for any medical use or uses of radioactive material specified in Rule [.05](#) of this Chapter, will be approved if:

(i) The applicant satisfies the requirements of (9)(b), (c), or (d);

(ii) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses specified in the application;

(iii) The applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, has adequate training and experience in the handling of radioactive material appropriate to his participation in the uses specified in the application;

(iv) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses specified in the application;

(v) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses specified in the application; and

(vi) For uses regulated by Rules [.05\(41\) and \(44\)](#) of this Chapter, any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

- (I) Chemical and physical form,
- (II) Route of administration, and
- (III) Dosage range.

2. Any licensee who is authorized to use radioactive material pursuant to (9)(e) and to Rule [.05](#) of this Chapter is subject to the following conditions:

(i) For paragraphs (41), (44), and (48) of Rule [.05](#) of this Chapter, no licensee shall receive, possess, or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, and labeled, packaged, and distributed in accordance with a specific license issued by the Director pursuant to (11)(i), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section [32.72](#) of 10 CFR, Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(ii) For Rule [391-3-17-.05\(44\)](#), no licensee shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(I) Reagent kits not containing radioactive material that are approved by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State for use by persons licensed pursuant to (9)(d) and to Rule [.05](#) of this Chapter or

(II) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Director pursuant to (11)(i), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section [32.73](#) of 10 CFR, Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations; and

(iii) For Brachytherapy, regulated by Rule [.05](#) of this Chapter, no licensee shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Director pursuant to (11)(j), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section [32.74](#) of 10 CFR, Part 32, or a specific license issued to the manufacturer by an Agreement State or a Licensing State pursuant to equivalent regulations.

3. Any licensee who is licensed pursuant to (9) for one or more of the medical uses regulated by Rule [.05](#) of this Chapter also is authorized to use radioactive material under the general license in (6)(g) for in vitro uses without filing the Certificate as required by (6)(g)2, provided that the licensee is subject to the other provisions of (6)(g).

(f) Use of Naturally-Occurring Radioactive Material (NORM). In addition to the requirements set forth in (8), a specific license for the use of NORM will be issued if the licensee meets all of the requirements of Rule [.08](#) of this Chapter.

(g) Use of Sealed Sources in Irradiators. In addition to the requirements set forth in (8), a specific license for the use of sealed sources in large irradiators will be issued if the licensee meets all of the requirements of Rule [.09](#) of this Chapter.

(10) **Special Requirements for Specific Licenses of Broad Scope.** These requirements are for the issuance of non-medical specific licenses of broad scope for radioactive material ("broad licenses") and contain certain regulations governing holders of such licenses. (The issuance of medical specific licenses of broad scope is addressed in (9).)

*Nota Bene:* See Note, in (3)(c)1.

(a) The different types of broad scope licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in (21)(c), Schedule C, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in (21)(c), Schedule C, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in (21)(c), Schedule C, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in (21)(c), Schedule C, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in (21)(c), Schedule C, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in (21)(c), Schedule C, Column II, for that radionuclide. The sum of the ratios for all radio nuclides possessed under the license shall not exceed unity.

(b) An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in (8);
2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record-keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The establishment of a Radiation Safety Committee composed of such persons as a Radiation Safety Officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(ii) The appointment of a Radiation Safety Officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) The establishment of appropriate administrative procedures to assure:

(I) Control of procurement and use of radioactive material;

(II) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, the training and experience of the user, and the operating or handling procedures; and

(III) Review, approval, and recording by the Radiation Safety Committee of safety evaluations of proposed uses prepared in accordance with (10)(b)3.(iii)(II) prior to the use of the radioactive material.

(c) An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in (8); and

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record-keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The appointment of a Radiation Safety Officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(ii) The establishment of appropriate administrative procedures to assure:

(I) Control of procurement and use of radioactive material,

(II) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, the training and experience of the user, and the operating or handling procedures, and

(III) Review, approval, and recording by the Radiation Safety Officer of safety evaluations of proposed uses prepared in accordance with (10)(c)2.(ii)(II) prior to the use of the radioactive material.

(d) An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in (8);

2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

(ii) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record-keeping, material control and accounting, and management review necessary to assure safe operations.

(e) Specific non-medical licenses of broad scope are subject to the following conditions:

1. Unless specifically authorized, persons licensed pursuant to (10) shall not:

(i) Conduct tracer studies in the environment involving direct release of radioactive material;

(ii) Receive, acquire, own, possess, use, or transfer devices containing 100,000 Curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) Conduct activities for which a specific license issued by the Division under (9) or (11) is required; or

(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

2. Each Type A specific license of broad scope issued under (10) shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's Radiation Safety Committee.

3. Each Type B specific license of broad scope issued under (10) shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's Radiation Safety Officer.

4. Each Type C specific license of broad scope issued under (10) shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of (10)(d).

**(11) Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

(a) [Reserved]

(b) Licensing the Distribution of Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) in Exempt Quantities.

*Nota Bene:* See Note, in (3)(c)1.

1. An application for a specific license to distribute NARM to persons exempted from this Chapter pursuant to (3)(b) will be approved if:

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) The radioactive material is in the form of processed chemical elements, compounds, mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) The applicant submits copies of prototype labels and brochures and the Division approves such labels and brochures.

2. The license issued under (11)(b)1. is subject to the following conditions:

(i) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to (3)(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5  $\mu$ Sv) per hour.

(iii) The immediate container of each quantity or separately-packaged fractional quantity of radioactive material shall bear a durable and legible label which:

(I) Identifies the radionuclide and the quantity of radioactivity, and

(II) Bears the words "Radioactive Material".

(iv) In addition to the labeling information required by (11)(b)2.(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(I) State that the contents are exempt from Licensing State requirements,

(II) Bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined", and

(III) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3. Each person licensed under (11)(b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under (3)(b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Division. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to (11)(b) during the reporting period, the report shall so indicate.

(c) [Reserved]

(d) Licensing the Manufacture and Initial Transfer of Devices to Persons Generally Licensed Under (6)(c).

1. An application for a specific license to initially transfer devices containing radioactive material to persons generally licensed under (6)(c) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

(i) The applicant satisfies the general requirements of (8);

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(I) The device can be safely operated by persons not having training in radiological protection,

(II) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of ten percent of the annual limits specified in Rule [.03\(5\)\(a\)1.](#) of this Chapter, and

(III) Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

I. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye

15 rem (150 mSv);

II. Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter

200 rem (2 Sv);

III. Other Organs

50 rem (500 mSv); and

(iii) Each device bears a durable, legible, and clearly visible label or labels approved by the Division, which contain in a clearly identified and separate statement:

(I) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(II) The requirement, or lack of requirement, for leak testing, or for testing any on/off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(III) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

I. The receipt, possession, use, and transfer of this device, Model \_\_\_\_\_, Serial No.\_\_\_\_\_, are subject to a general license or the equivalent and to the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

\_\_\_\_\_  
(NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

II. The receipt, possession, use, and transfer of this device, Model \_\_\_\_\_, Serial No.\_\_\_\_\_, are subject to a general license or the equivalent, and to the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

\_\_\_\_\_  
(NAME OF MANUFACTURER OR INITIAL TRANSFEROR)

Note: The model, serial number, and name of the manufacturer or distributor may be omitted from the appropriate label provided the information is elsewhere specified in labeling affixed to the device. Devices distributed pursuant to Regulations equivalent to (11)(d) prior to January 1, 1981, may bear labels authorized by the Regulations in effect on January 1, 1980. Devices distributed on or after January 1, 1981, including devices redistributed upon radioactive sources exchange, shall bear labels authorized in (11)(d).

(iv) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in Rule [.03\(12\)](#), and the name of the manufacturer or initial distributor.

(v) Each device meeting the criteria of (6)(c)3.(xii), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practical, the radiation symbol described in Rule [.03\(12\)](#).

(vi) The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be tested at intervals longer than six months, either for proper operation of the on/off mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on/off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Division will consider information that includes, but is not limited to:

- (i) Primary containment (source capsule);
- (ii) Protection of primary containment;
- (iii) Method of sealing containment;
- (iv) Containment construction materials;
- (v) Form of contained radioactive material;
- (vi) Maximum temperature withstood during prototype tests;
- (vii) Maximum pressure withstood during prototype tests;
- (viii) Maximum quantity of contained radioactive material;
- (ix) Radiotoxicity of contained radioactive material; and
- (x) Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under (6)(c), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on/off mechanism and indicator, or remove the device from installation, the applicant shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the basis for such estimates. The submitted information shall demonstrate that the performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in Rule [.03\(5\)\(a\)1.](#) of this Chapter.

4. Each person licensed under (11)(d) shall provide the information specified in (11)(d)4.(i) to each generally licensed recipient to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person.

(i) The required information includes:

(I) A copy of the general license contained in (6)(c); if (6)(c)3.(ii) through (iv) or (6)(c)3.(xii) do not apply to the particular device, these rules may be omitted.

(II) A copy of Rule [.01\(4\), \(5\), \(6\), \(7\), \(8\), \(9\) and \(10\)](#), Rule [.02\(13\), \(18\), and \(19\)](#), Rule [.03\(15\)\(a\) and \(b\)](#) and Rule [.06](#);

(III) A list of the services that can only be performed by a specific licensee;

(IV) Information on acceptable disposal options including estimated costs of disposal; and

(V) An indication that improper disposal can result in high civil penalties.

(ii) If a device containing radioactive material is to be transferred for use under a general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to (6)(c), the licensee shall provide the information specified in (11)(d)4.(ii) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(I) A copy of this equivalent regulation or, alternatively, furnish a copy of the general license contained in (6)(c) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State, or the Licensing State. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. If a copy of the general license in (6)(c) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State under requirements substantially the same as those in (6)(c); if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(II) A list of the services that can only be performed by a specific licensee;

(III) Information on acceptable disposal options including estimated costs of disposal;

(IV) An indication that improper disposal can result in high civil penalties; and

(V) The name or title, address, and telephone number of the contact at the appropriate NRC Regional Office or Agreement State from which additional information may be obtained.

(iii) An alternative approach to informing customers may be proposed by the licensee for approval by the Division.

5. Each device that is transferred after January 1, 2003, must meet the labeling requirements of (11)(d)1.(iii) through (v).

6. If a notification of bankruptcy has been made under (13)(e) or the license is to be terminated, each person licensed under (11)(d) shall provide, upon request, to the Division and as appropriate to any Agreement State or the NRC, records of final disposition required under (11)(d)4.(viii).

7. The licensee shall report to the Division all transfers of such devices to persons for use under the general license in (6)(c) and report all receipts of such devices from persons licensed under (6)(c).

(i) Such report shall identify each general licensee by the following:

(I) The name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

(II) The name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of the transfer;

(IV) The type, model number, and serial number of the device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) For devices received from a (6)(c) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a (6)(c) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(v) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(vi) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(vii) If no transfers have been made to or from persons generally licensed under (6)(c) during the reporting period, the report shall so indicate.

8. The licensee shall furnish reports to other agencies as follows:

(i) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section [31.5](#) of 10 CFR, Part 31 and all receipts of devices from U.S. Nuclear Regulatory Commission Section 31.5 general licensees;

(ii) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to (11)(d) for use under a general license in that state's regulations equivalent to (6)(c) and all receipts of devices from general licensees in the state agency's jurisdiction;

(iii) The reports identified in 8.(i) and 8.(ii) shall identify each general licensee by the following:

(I) The name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(II) The name, title and telephone number the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(III) The date of the transfer;

(IV) The type, model, and serial number of the device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(iv) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(v) For devices received from a (6)(c) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(vi) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(vii) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(viii) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(ix) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, report this information to the U.S. Nuclear Regulatory Commission; and

(x) If no transfers have been made to general licensees within a particular state during the reporting period, report this information to the responsible state agency upon request of that agency.

9. Each person licensed under (11)(d) to distribute devices to generally licensed persons shall maintain all information concerning transfers and receipts of devices that supports the reports required by (11)(d)4. These records shall be maintained for a period of three years following the date of the recorded event.

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, and for distribution to persons generally licensed under (6)(d), will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in (8), and
2. The applicant satisfies the requirements of Sections [32.53](#), [32.54](#), [32.55](#), and [32.56](#) of 10 CFR, Part 32, or their equivalent.

(f) Special Requirements for License to Manufacture or Initially Transfer Calibration Sources Containing Americium-241, Plutonium, or Radium-226 for Distribution to Persons Generally Licensed Under (6)(f). An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium, or radium-226 to persons generally licensed under (6)(f) will be approved subject to the following conditions:

1. The applicant satisfies the general requirement of (8), and
2. The applicant satisfies the requirements of Sections [32.57](#), [32.58](#), and [32.59](#) of 10 CFR, Part 32, and Section [70.39](#) of 10 CFR, Part 70, or their equivalent.

(g) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of (6)(g) will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in (8);
2. The radioactive material is to be prepared for distribution in prepackaged units of:

(i) Iodine-125 in units not exceeding ten microcuries (370 kBq) each,

(ii) Iodine-131 in units not exceeding ten microcuries (370 kBq) each,

(iii) Carbon-14 in units not exceeding ten microcuries (370 kBq) each,

(iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each,

(v) Iron-59 in units not exceeding 20 microcuries (740 kBq) each,

(vi) Cobalt-57 in units not exceeding ten microcuries (370 kBq) each,

(vii) Selenium-75 in units not exceeding ten microcuries (370 kBq) each,

(viii) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each;

3. Each prepackaged unit bears a durable and clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 Mbq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(ii) Displaying the radiation caution symbol described in Rule [391-3-17-.03](#), of this Chapter, and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals";

4. One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations of and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

\_\_\_\_\_  
(NAME OF MANUFACTURER)

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations of and a general license of a Licensing State.

\_\_\_\_\_  
(NAME OF MANUFACTURER)

and

5. The label affixed to the unit, or the leaflet or brochure, which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule [.03\(13\)](#) of this Chapter.

(h) Licensing the Manufacture and Distribution of Ice-Detection Devices. An application for a specific license to manufacture and initially transfer ice-detection devices to persons generally licensed under (6)(e) will be approved subject to the following conditions:

1. The applicant satisfies the general requirements of (8), and
2. The criteria of Sections [32.61](#) and [32.62](#) of 10 CFR, Part 32, are met.

(i) Manufacture, Preparation, or Transfer, for Commercial Distribution of Pharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture, prepare, or transfer for commercial distribution pharmaceuticals containing radioactive material for use by persons licensed pursuant to (9) for the uses listed in (41), (44), and (48) of Rule [.05](#) of this Chapter will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in (8);

2. The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under [21 CFR 207.20\(a\)](#);

(ii) Registered or licensed with a State Agency as a drug manufacturer;

(iii) Licensed as a pharmacy by the Georgia State Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical, and shielding provided by the packaging to show it is appropriate for safe handling and storage of radiopharmaceuticals by licensees; and

4. The applicant commits to the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical to be transferred for commercial distribution. The label must include the radiation symbol and words "Caution, Radioactive Material" or "Danger Radioactive Material"; the name of the radiopharmaceutical or its abbreviation, and quantity of radioactivity at a specified date and time. For radiopharmaceuticals with a half-life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical to be transferred for commercial distribution. The label must include the words "Caution, Radioactive Material" or "Danger Radioactive Material" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label, leaflet, or brochure.

5. A licensee described by (11)(i)2.(iii) or (iv):

(i) May prepare radiopharmaceuticals for medical use, as defined in Rule [.05\(2\)\(s\)](#) provided that the radiopharmaceutical is prepared by either an authorized nuclear pharmacist, as specified in (ii) and (iv) or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule [.05\(18\)\(b\)](#).

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if this individual:

(I) Qualifies as an authorized nuclear pharmacist as defined in [.05\(2\)\(e\)](#),

(II) Meets the requirements specified in Rule [.05\(24\)\(b\)](#) and [.05\(27\)](#) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or has notified the Division in accordance with Rule [.05\(11\)](#), or

(III) Is designated as an authorized nuclear pharmacist in accordance with (iv).

(iii) The actions authorized in (i) and (ii) are permitted notwithstanding more restrictive language in license conditions.

(iv) May designate a nuclear pharmacist in accordance with Rule [.05\(26\)](#) as an authorized nuclear pharmacist if the individual is identified as of December 31, 1996, as an "authorized user" on a license issued by the Director, the NRC, or an Agreement State, under this rule or equivalent requirements, or if the individual was a nuclear pharmacist preparing only radiopharmaceuticals containing accelerator produced radioactive material and the individual practiced at a Government Agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(v) Shall provide to the Division a copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in [391-3-17-.05\(24\)](#), or a Division, NRC, or Agreement State issued license, or permit issued by a licensee of broad scope, or documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and a copy of the individual's license to practice pharmacy in the State of Georgia issued by the Secretary of State's office, no later than 30 days after the date that the licensee allows pursuant to (ii) and (iii), the individual to work as an authorized nuclear pharmacist.

6. A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall measure, by direct measurements or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals prior to transfer for commercial distribution. In addition, the licensee shall:

(i) Perform test before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(ii) Check each instrument for constancy and proper operation at the beginning of each day of use.

7. A licensee shall satisfy the labeling requirements in subparagraph (11)(i)4.

8. Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, or other State requirements governing radiopharmaceuticals.

(j) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Rule [.05](#) of this chapter for use as a calibration, transmission, or reference source or for medical uses regulated by Rule [.05\(55\)](#), [\(65\)](#), or [\(67\)](#) of this Chapter will be approved subject to the following conditions:

1. The applicant satisfies the general requirements of (8);

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The radioactive material contained, its chemical and physical form, and amount,

(ii) Details of design and construction of the source or device,

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) For devices containing radioactive material, the radiation profile of a prototype device,

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) Procedures and standards for calibrating sources and devices,

(vii) Legend and methods for labeling sources and devices as to their radioactive content, and

(viii) Instructions for handling and storing the source or device from the radiation safety standpoint. (These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device. Instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure that is referenced on the label.)

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Director for distribution to persons licensed pursuant to (9) and to Rule [.05\(55\), \(65\), or \(67\)](#) of this Chapter or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State;

4. The source or device has been registered in the Sealed Source and Device Registry;

5. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source;

6. In determining the acceptable interval for test of leakage of radioactive material, the Division will consider information that includes, but is not limited to, that which is listed in (11)(d)2.

(k) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to (5)(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved subject to the following conditions:

(i) The applicant satisfies the general requirements specified in (8);

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 year a radiation dose in excess of ten percent of the annual limits specified in Rule [.03\(5\)\(a\)1.](#) of this Chapter; and

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the Director will approve an application for a specific license under (11)(k) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The Director may deny any application for a specific license under (11)(k) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to (11)(k)1. shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(I) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(II) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and to the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;

(iii) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv) Furnish a copy of the general license contained in:

(I) (5)(d) and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License" to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in (5)(d), or

(II) The U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to (5)(d) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or, alternatively, furnish a copy of the general license contained in (5)(d) and a copy of Division form "Registration Certificate - Use of Depleted Uranium Under General License" to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in (5)(d);

(v) Report to the Division all transfers of industrial products or devices to persons for use under the general license in (5)(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Division and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under (5)(d) during the reporting period, the report shall so indicate;

(vi) Report to other agencies as follows:

(I) To the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Regulatory Commission general license in Section [40.25](#) of 10 CFR, Part 40;

(II) To the responsible state agency all transfers of devices manufactured and distributed pursuant to [10 CFR 32.210](#) for use under a general license in that state's regulations equivalent to (5)(d);

(III) Have such reports identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

(IV) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, report this information to the U.S. Nuclear Regulatory Commission; and

(V) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, report this information to the responsible Agreement State agency upon the request of that agency; and

(vii) Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in (5)(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of (11).

(l) [Reserved]

**(12) Issuance of Specific Licenses.**

(a) Upon a determination that an application meets the requirements of the Act and the Rules of the Division, the Director may issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the Act.

(b) The Director may incorporate in any license at the time of issuance, or thereafter, such additional requirements and conditions, as authorized by the Act or Rules, or Order, with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this Chapter as necessary in order to:

1. Minimize danger to public health and safety or property;
2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as necessary to effectuate the purposes of the Act; and
3. Prevent loss or theft of material subject to this Rule.

**(13) Specific Terms and Conditions of Licenses.**

(a) Each license issued pursuant to this Rule shall be subject to all the provisions of the Act, and to all Rules of the Division and Orders of the Director.

(b) No license issued or granted under this Rule and no right to possess or utilize radioactive material granted by any license issued pursuant to this Rule shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Division, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

1. An application for transfer of license must include:

(i) The identity, technical and financial qualification of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by [.02\(8\)\(g\)](#).

(c) Each person licensed by the Director pursuant to this Rule shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Division in writing immediately and request termination of his license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. This notification and request for termination must include the information specified in (18)(d).

(e) Each general licensee required to register by (6)(c)3.(xi) and each specific licensee shall notify the Division in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;

2. An entity (as that term is defined in [11 U.S.C. 101\(15\)](#)) controlling the licensee or listing the license or licensee as property of the estate; or

3. An affiliate (as that term is defined in [11 U.S.C. 101\(2\)](#)) of the licensee.

(f) The notification specified in (13)(e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(g) Security requirements for portable gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(h) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule [.05\(45\)\(a\)\(b\) and \(c\)](#). The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in [391-3-17-.05\(45\)](#) at the time of generator elution, in accordance with [391-3-17-.05\(120\)](#).

(i) Authorization under [.02\(7\)\(j\)](#) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

1. Each licensee authorized under [.02\(7\)\(j\)](#) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in [.02\(11\)\(i\)4.](#) of this Rule for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in [.02\(11\)\(i\)6.](#) of this Rule.

2. A licensee that is a pharmacy authorized under [.02\(7\)\(j\)](#) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in [.02\(11\)\(i\)5.](#) of this Rule, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule [.05\(18\)](#).

3. A pharmacy, authorized under [.02\(7\)\(j\)](#) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of [.02\(11\)\(i\)5.\(v\)](#) of this Rule.

(14) **Expiration of Licenses.** Except as provided in (15)(b), each specific license shall expire at the end of the day, in the month and year stated therein.

(15) **Renewal of Licenses.**

(a) No less than 30 days before the expiration date specified in a specific license, the licensee shall either:

1. Submit an application for license renewal filed in accordance with (7), or

2. Notify the Division in writing in accordance with (13)(d) and (15)(c) if the licensee decides not to renew the license.

(b) In any case in which a licensee, not less than 30 days prior to the expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Division.

(c) If a licensee does not submit an application for license renewal on or before the expiration date specified in the license, then the licensee shall, on or before that expiration date:

1. Terminate the use of radioactive material,
2. Remove radioactive contamination to the extent practicable,
3. Properly dispose of the radioactive material, and
4. Submit the information specified in (18)(d).

(16) **Amendment of Licenses at Request of Licensee.** Applications for amendment of a license shall be filed in accordance with (7) and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

(17) **Action on Applications to Renew or Amend.** In considering an application by a licensee to renew or amend the license, the Director will apply the criteria set forth in (8), (9), (10), or (11), as applicable.

(18) **Modification, Revocation, and Termination of Licenses.**

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification, or the license may be suspended or revoked by reason of amendments to the Act, or by reason of Rules, and Orders issued by the Director.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or of this Rule, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Director to refuse to grant a license on an original application, or for violation of, or failure to observe, any of the terms and conditions of the Act, of the license, or of any Rule or Order of the Director.

(c) Each specific license revoked by the Director expires at the end of the day on the date of the Director's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Order of the Director.

(d) The Director may terminate a specific license upon request submitted by the licensee to the Division in writing provided the following:

1. The licensee certifies the disposition of all licensed material, including accumulated wastes, by submitting a completed "Request to Terminate Radioactive Materials License" form or equivalent information; and
2. The licensee conducts a radiation survey of the premises where the licensed activities were carried out and submits a report of the results of the survey unless the licensee demonstrates that the premises are suitable for release in accordance with the requirements for decommissioning in Rule [.03\(7\)](#). As appropriate, the licensee shall:
  - (i) Report levels of gamma radiation in units of microroentgen (millisieverts) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters - removable and fixed - for surfaces, microcuries (megabecquerels) per milliliter for water, and picocuries (becquerels) per gram for solids such as soils or concrete; and
  - (ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.
3. If detectable levels of residual radioactive contamination are found, the license continues to be in effect, even beyond the expiration date if necessary, with respect to possession of residual radioactive material as contamination until the Division notifies the licensee in writing that the license is terminated. Each licensee who possesses residual radioactive material under this paragraph shall initiate decommissioning activities as required by (8)(h).

4. If no residual radioactive contamination is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the information submitted is found to be adequate, the Director will notify the licensee in writing that the license is terminated.

(e) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Director determines that:

1. Radioactive material has been properly disposed;
2. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and
3. (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Division requirements for decommissioning in Rule [.03\(7\)](#); or  
(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Division requirements for decommissioning in Rule [.03\(7\)](#).

4. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Division:

(i) Records of disposal of licensed material made under Rule [.03\(13\)\(b\)](#) (including burials authorized before January 28, 1982), [.03\(13\)\(c\)](#), [.03\(13\)\(d\)](#), [.03\(13\)\(e\)](#); and

(ii) Records required by Rule [.03\(14\)\(c\)2.\(iv\)](#).

5. If licensed activities are transferred or assigned in accordance with Rule [.02\(13\)\(b\)](#), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(i) Records of disposal of licensed material made under Rule [.03\(13\)\(b\)](#) (including burials authorized before January 28, 1982), [.03\(13\)\(c\)](#), [.03\(13\)\(d\)](#), [.03\(13\)\(e\)](#); and

(ii) Records required by Rule [.03\(14\)\(c\)2.\(iv\)](#).

6. Prior to license termination, each licensee shall forward the records required by Rule [.02\(8\)\(g\)8](#), to the Division.

#### **(19) Transfer of Material.**

(a) Authorization for Transfer. No licensee shall transfer radioactive material except as authorized pursuant to (19)(b).

(b) Condition of Transfer. Any licensee may transfer radioactive material, subject to acceptance by the transferee, to:

1. The Division, after receiving prior approval from the Division;
2. The United States Department of Energy or any successor thereto;
3. Any person exempt from this Rule to the extent permitted under such exemption;
4. Any person licensed to receive such material under terms of a general license or its equivalent, or specific license or equivalent licensing document issued by the Director, the U.S. Nuclear Regulatory Commission, any Agreement State, or any Licensing State, to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Division, any Agreement State, or any Licensing State; or
5. Any person authorized by the Division in writing.

(c) Before transferring radioactive material to a specific licensee of the Director, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or to a general licensee who is required to register with the Division, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by (19)(c) are acceptable:

1. The transferor may possess, and read, a current copy of the transferee's specific license or registration certificate.
2. The transferor may have in his possession a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.
3. For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided that the oral certification is confirmed in writing within ten days.
4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Division, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration date of licenses and registration.
5. When none of the methods of verification described in paragraphs (19)(d)1., 2., 3., and 4. is readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Division, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Rule [.06](#) of this Chapter.

(f) Each person who receives source or byproduct material pursuant to a license issued pursuant to the regulations in Rule [391-3-17-.02](#) shall keep records showing the receipt, transfer, and disposal of this source or byproduct material as specified in [10 CFR 40.61](#).

**(20) Reciprocity.**

(a) Persons licensed by other Agencies. Subject to the provisions of this Chapter, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, a Licensing State, or any Agreement State, other than this State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State, except in areas of exclusive federal jurisdiction, for a period not in excess of 180 days in any calendar year provided that:

1. The licensing document does not limit the activity authorized by such document to specified installations or locations;
2. The out-of-state licensee notifies the Division in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Division, obtain permission to proceed sooner;

3. The out-of-state licensee complies with all applicable Rules of the Division, and with all the terms and conditions of his licensing document except any such terms and conditions that may be inconsistent with applicable Rules of the Division;

4. Provided further that the Division may require the out-of-state licensee to supply such other information as the Division may reasonably request; and

5. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in (20)(a) except by transfer to a person who is:

(i) Specifically licensed by the Director, the U.S. Nuclear Regulatory Commission, or by another Licensing State to receive such material; or

(ii) Exempt from the requirements for a license for such material under (3)(a).

(b) Notwithstanding the provisions of (20)(a), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in (6)(c)1. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such device in this State provided that:

1. Such person shall file a report with the Division within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such a device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State;

3. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed the manufacturing of the device bear a statement that "Removal of This Label is Prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom he transfers such a device or on whose premises he installs such a device a copy of the general license contained in (6)(c).

(c) The Division may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety, to property, or to the environment.

**(21) Schedules.**

(a) Schedule A.

**SCHEDULE A  
EXEMPT CONCENTRATIONS**

| <b>Exempt Concentrations</b>   | <b>Schedule A</b> | <b>Column I<br/>Gas Concentration<br/>(<math>\mu\text{Ci}/\text{mL}</math>)<sup>(1)</sup></b> | <b>Column II<br/>Liquid and Solid<br/>Concentration (<math>\mu\text{Ci}/\text{mL}</math>)<sup>(2)</sup></b> |
|--------------------------------|-------------------|---|---|
| <b>Element (Atomic Number)</b> | <b>Isotope</b>    |   |   |
| Antimony (51)                  | Sb 122            |   | $3 \times 10^{-4}$  |
|                                | Sb 124            |   | $2 \times 10^{-4}$  |
|                                | Sb 125            |   | $1 \times 10^{-3}$  |
| Argon (18)                     | Ar 37             | $1 \times 10^{-3}$  |   |
|                                | Ar 41             | $4 \times 10^{-7}$  |   |

| Exempt Concentrations                          | Schedule A | Column I<br>Gas Concentration<br>( $\mu\text{Ci/mL}$ ) <sup>(1)</sup> | Column II<br>Liquid and Solid<br>Concentration ( $\mu\text{Ci/mL}$ ) <sup>(2)</sup> |
|--|------------|---|---|
| Element (Atomic Number)                        | Isotope    |   |   |
| Arsenic (33)                                   | As 73      |   | $5 \times 10^{-3}$  |
|  | As 74      |   | $5 \times 10^{-4}$  |
|  | As 76      |   | $2 \times 10^{-4}$  |
|  | As 77      |   | $8 \times 10^{-4}$  |
| Barium (56)                                    | Ba 131     |   | $2 \times 10^{-3}$  |
|  | Ba 140     |   | $3 \times 10^{-4}$  |
| Beryllium (4)                                  | Be 7       |   | $2 \times 10^{-2}$  |
| Bismuth (83)                                   | Bi 206     |   | $4 \times 10^{-4}$  |
| Bromine (35)                                   | Br 82      | $4 \times 10^{-7}$  | $3 \times 10^{-3}$  |
| Cadmium (48)                                   | Cd 109     |   | $2 \times 10^{-3}$  |
|  | Cd 115m    |   | $3 \times 10^{-4}$  |
|  | Cd 115     |   | $3 \times 10^{-4}$  |
| Calcium (20)                                   | Ca 45      |   | $9 \times 10^{-5}$  |
|  | Ca 47      |   | $5 \times 10^{-4}$  |
| Carbon (6)                                     | C 14       | $1 \times 10^{-6}$  | $8 \times 10^{-3}$  |
| Cerium (58)                                    | Ce 141     |   | $9 \times 10^{-4}$  |
|  | Ce 143     |   | $4 \times 10^{-4}$  |
|  | Ce 144     |   | $1 \times 10^{-4}$  |
| Cesium (55)                                    | Cs 131     |   | $2 \times 10^{-2}$  |
|  | Cs 134m    |   | $6 \times 10^{-2}$  |
|  | Cs 134     |   | $9 \times 10^{-5}$  |
| Chlorine (17)                                  | Cl 38      | $9 \times 10^{-7}$  | $4 \times 10^{-3}$  |
| Chromium (24)                                  | Cr 51      |   | $2 \times 10^{-2}$  |
| Cobalt (27)                                    | Co 57      |   | $5 \times 10^{-3}$  |
|  | Co 60      |   | $5 \times 10^{-4}$  |
| Copper (29)                                    | Cu 64      |   | $3 \times 10^{-3}$  |
| Dysprosium (66)                                | Dy 165     |   | $4 \times 10^{-3}$  |
|  | Dy 166     |   | $4 \times 10^{-4}$  |
| Erbium (68)                                    | Er 169     |   | $9 \times 10^{-4}$  |
|  | Er 171     |   | $1 \times 10^{-3}$  |
| Europium (63)<br>( $T^{0.5} = 9.2 \text{ h}$ ) | Eu 152     |   | $6 \times 10^{-4}$  |
|  | Eu 155     |   | $2 \times 10^{-3}$  |
| Fluorine (9)                                   | F 18       | $2 \times 10^{-6}$  | $8 \times 10^{-3}$  |
| Gadolinium (64)                                | Gd 153     |   | $2 \times 10^{-3}$  |
|  | Gd 159     |   | $8 \times 10^{-4}$  |
| Gallium (31)                                   | Ga 72      |   | $4 \times 10^{-4}$  |
| Germanium (32)                                 | Ge 71      |   | $2 \times 10^{-2}$  |
| Gold (79)                                      | Au 196     |   | $2 \times 10^{-3}$  |
|  | Au 198     |   | $5 \times 10^{-4}$  |
|  | Au 199     |   | $2 \times 10^{-3}$  |
| Hafnium (72)                                   | Hf 181     |   | $7 \times 10^{-4}$  |
| Hydrogen (1)                                   | H 3        | $5 \times 10^{-6}$  | $3 \times 10^{-2}$  |
| Indium (49)                                    | In 113m    |   | $1 \times 10^{-2}$  |
|  | In 114m    |   | $2 \times 10^{-4}$  |
| Iodine (53)                                    | I 126      | $3 \times 10^{-9}$  | $2 \times 10^{-5}$  |
|  | I 131      | $3 \times 10^{-9}$  | $2 \times 10^{-5}$  |
|  | I 132      | $8 \times 10^{-8}$  | $6 \times 10^{-4}$  |
|  | I 133      | $1 \times 10^{-8}$  | $7 \times 10^{-5}$  |
|  | I 134      | $2 \times 10^{-7}$  | $1 \times 10^{-3}$  |
| Iridium (77)                                   | Ir 190     |   | $2 \times 10^{-3}$  |
|  | Ir 192     |   | $4 \times 10^{-4}$  |
|  | Ir 194     |   | $3 \times 10^{-4}$  |

| Exempt Concentrations       | Schedule A | Column I<br>Gas Concentration<br>( $\mu\text{Ci/mL}$ ) <sup>(1)</sup> | Column II<br>Liquid and Solid<br>Concentration ( $\mu\text{Ci/mL}$ ) <sup>(2)</sup> |
|-----------------------------|------------|---|---|
| Element (Atomic Number)     | Isotope    |   |   |
| Iron (26)                   | Fe 55      |   | $8 \times 10^{-3}$  |
|                             | Fe 59      |   | $6 \times 10^{-4}$  |
| Krypton (36)                | Kr 85m     | $1 \times 10^{-6}$  |   |
|                             | Kr 85      | $3 \times 10^{-6}$  |   |
| Lanthanum (57)              | La 140     |   | $2 \times 10^{-4}$  |
| Lead (82)                   | Pb 203     |   | $4 \times 10^{-3}$  |
| Lutetium (71)               | Lu 177     |   | $1 \times 10^{-3}$  |
| Manganese (25)              | Mn 52      |   | $3 \times 10^{-4}$  |
|                             | Mn 54      |   | $1 \times 10^{-3}$  |
|                             | Mn 56      |   | $1 \times 10^{-3}$  |
| Mercury (80)                | Hg 197m    |   | $2 \times 10^{-3}$  |
|                             | Hg 197     |   | $3 \times 10^{-3}$  |
|                             | Hg 203     |   | $2 \times 10^{-4}$  |
| Molybdenum (42)             | Mo 99      |   | $2 \times 10^{-3}$  |
| Neodymium (60)              | Nd 147     |   | $6 \times 10^{-4}$  |
|                             | Nd 149     |   | $3 \times 10^{-3}$  |
| Nickel (28)                 | Ni 65      |   | $1 \times 10^{-3}$  |
| Niobium<br>(columbium) (41) | Nb 95      |   | $1 \times 10^{-3}$  |
|                             | Nb 97      |   | $9 \times 10^{-3}$  |
|                             | Os 185     |   | $7 \times 10^{-4}$  |
| Osmium (76)                 | Os 191m    |   | $3 \times 10^{-2}$  |
|                             | Os 191     |   | $2 \times 10^{-3}$  |
|                             | Os 193     |   | $6 \times 10^{-4}$  |
|                             | Pd 103     |   | $3 \times 10^{-3}$  |
| Palladium (46)              | Pd 109     |   | $9 \times 10^{-4}$  |
|                             | P 32       |   | $2 \times 10^{-4}$  |
| Phosphorus (15)             |            |   |   |
| Platinum (78)               | Pt 191     |   | $1 \times 10^{-3}$  |
|                             | Pt 193m    |   | $1 \times 10^{-2}$  |
|                             | Pt 197m    |   | $1 \times 10^{-2}$  |
|                             | Pt 197     |   | $1 \times 10^{-3}$  |
| Polonium (84)               | Po 210     |   | $7 \times 10^{-6}$  |
| Potassium (19)              | K 42       |   | $3 \times 10^{-3}$  |
| Praseodymium (59)           | Pr 142     |   | $3 \times 10^{-4}$  |
|                             | Pr 143     |   | $5 \times 10^{-4}$  |
| Promethium (61)             | Pm 147     |   | $2 \times 10^{-3}$  |
|                             | Pm 149     |   | $4 \times 10^{-4}$  |
| Radium (88)                 | Ra 226     |   | $1 \times 10^{-7}$  |
|                             | Ra 228     |   | $3 \times 10^{-7}$  |
| Rhenium (75)                | Re 183     |   | $6 \times 10^{-3}$  |
|                             | Re 186     |   | $9 \times 10^{-4}$  |
|                             | Re 188     |   | $6 \times 10^{-4}$  |
| Rhodium (45)                | Rh 103m    |   | $1 \times 10^{-1}$  |
| Rubidium (37)               | Rb 86      |   | $7 \times 10^{-4}$  |
| Ruthenium (44)              | Ru 97      |   | $4 \times 10^{-3}$  |
|                             | Ru 103     |   | $8 \times 10^{-4}$  |
|                             | Ru 105     |   | $1 \times 10^{-3}$  |
|                             | Ru 106     |   | $1 \times 10^{-4}$  |
| Samarium (62)               | Sm 153     |   | $8 \times 10^{-4}$  |
| Scandium (21)               | Sc 46      |   | $4 \times 10^{-4}$  |
|                             | Sc 47      |   | $9 \times 10^{-4}$  |
|                             | Sc 48      |   | $3 \times 10^{-3}$  |
| Selenium (34)               | Se 75      |   | $3 \times 10^{-3}$  |

| Exempt Concentrations   | Schedule A | Column I<br>Gas Concentration<br>( $\mu\text{Ci/mL}$ ) <sup>(1)</sup> | Column II<br>Liquid and Solid<br>Concentration ( $\mu\text{Ci/mL}$ ) <sup>(2)</sup> |
|---|------------|---|---|
| Element (Atomic Number)   | Isotope    |   |   |
| Silicon (14)  | Si 31      |   | $9 \times 10^{-3}$  |
| Silver (47)   | Ag 105     |   | $1 \times 10^{-3}$  |
|   | Ag 110m    |   | $3 \times 10^{-4}$  |
|   | Ag 111     |   | $4 \times 10^{-4}$  |
| Sodium (11)   | Na 24      |   | $2 \times 10^{-3}$  |
| Strontium (38)  | Sr 85      |   | $1 \times 10^{-3}$  |
|   | Sr 89      |   | $1 \times 10^{-4}$  |
|   | Sr 91      |   | $7 \times 10^{-4}$  |
|   | Sr 92      |   | $7 \times 10^{-4}$  |
| Sulfur (16)   | S 35       | $9 \times 10^{-8}$  | $6 \times 10^{-4}$  |
| Tantalum (73)   | Ta 182     |   | $4 \times 10^{-4}$  |
| Technetium (43)   | Tc 96m     |   | $1 \times 10^{-1}$  |
|   | Tc 96      |   | $1 \times 10^{-3}$  |
| Tellurium (52)  | Te 125m    |   | $2 \times 10^{-3}$  |
|   | Te 127m    |   | $6 \times 10^{-4}$  |
|   | Te 127     |   | $3 \times 10^{-3}$  |
|   | Te 129m    |   | $3 \times 10^{-4}$  |
|   | Te 131m    |   | $6 \times 10^{-4}$  |
|   | Te 132     |   | $3 \times 10^{-4}$  |
| Terbium (65)  | Tb 160     |   | $4 \times 10^{-4}$  |
| Thallium (81)   | Tl 200     |   | $4 \times 10^{-3}$  |
|   | Tl 201     |   | $3 \times 10^{-3}$  |
|   | Tl 202     |   | $1 \times 10^{-3}$  |
|   | Tl 204     |   | $1 \times 10^{-3}$  |
| Thulium (69)  | Tm 170     |   | $5 \times 10^{-4}$  |
| Tin (50)  | Sn 113     |   | $9 \times 10^{-4}$  |
|   | Sn 125     |   | $2 \times 10^{-4}$  |
| Tungsten<br>(wolfram) (74)  | W 181      |   | $4 \times 10^{-3}$  |
|   | W 187      |   | $7 \times 10^{-4}$  |
| Vanadium (23)   | V 48       |   | $3 \times 10^{-4}$  |
| Xenon (54)  | Xe 131m    | $4 \times 10^{-6}$  |   |
|   | Xe 133     | $3 \times 10^{-6}$  |   |
|   | Xe 135     | $1 \times 10^{-6}$  |   |
| Ytterbium (70)  | Yb 175     |   | $1 \times 10^{-3}$  |
| Yttrium (39)  | Y 90       |   | $2 \times 10^{-4}$  |
|   | Y 91m      |   | $3 \times 10^{-2}$  |
|   | Y 91       |   | $3 \times 10^{-4}$  |
|   | Y 92       |   | $6 \times 10^{-4}$  |
|   | Y 93       |   | $3 \times 10^{-4}$  |
| Zinc (30)   | Zn 65      |   | $1 \times 10^{-3}$  |
|   | Zn 69m     |   | $7 \times 10^{-4}$  |
|   | Zn 69      |   | $2 \times 10^{-2}$  |
| Zirconium (40)  | Zr 95      |   | $6 \times 10^{-4}$  |
|   | Zr 97      |   | $2 \times 10^{-4}$  |
| Beta- and/or gamma-<br>emitting radioactive material<br>not listed above with half-<br>life less than three years |            | $1 \times 10^{-10}$   | $1 \times 10^{-6}$  |

Note: Many radioisotopes disintegrate into isotopes that are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters. For purposes of (3)(a) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:  $\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} +$

$\frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$

Footnotes:

(1) Values are given only for those materials normally used as gases.

(2)  $\mu\text{Ci/gm}$  for solids.

(b) Schedule B.

## SCHEDULE B EXEMPT QUANTITIES

### Schedule B - Exempt Quantities

| Radioactive Material   | Exempt Quantity (Microcuries) |
|------------------------|-------------------------------|
| Antimony-122 (Sb 122)  | 100                           |
| Antimony-124 (Sb 124)  | 10                            |
| Antimony-125 (Sb 125)  | 10                            |
| Arsenic-73 (As 73)     | 100                           |
| Arsenic-74 (As 74)     | 10                            |
| Arsenic-76 (As 76)     | 10                            |
| Arsenic-77 (As 77)     | 100                           |
| Barium-131 (Ba 131)    | 10                            |
| Barium-133 (Ba 133)    | 10                            |
| Barium-140 (Ba 140)    | 10                            |
| Bismuth-210 (Bi 210)   | 1                             |
| Bromine-82 (Br 82)     | 10                            |
| Cadmium-109 (Cd 109)   | 10                            |
| Cadmium-115m (Cd 115m) | 10                            |
| Cadmium-115 (Cd 115)   | 100                           |
| Calcium-45 (Ca 45)     | 10                            |
| Calcium-47 (Ca 47)     | 10                            |
| Carbon-14 (C 14)       | 100                           |
| Cerium-141 (Ce 141)    | 100                           |
| Cerium-143 (Ce 143)    | 100                           |
| Cerium-144 (Ce 144)    | 1                             |
| Cesium-129 (Cs 129)    | 100                           |
| Cesium-131 (Cs 131)    | 1,000                         |
| Cesium-134m (Cs 134m)  | 100                           |
| Cesium-134 (Cs 134)    | 1                             |
| Cesium-135 (Cs 135)    | 10                            |
| Cesium-136 (Cs 136)    | 10                            |
| Cesium-137 (Cs 137)    | 10                            |
| Chlorine-36 (Cl 36)    | 10                            |
| Chlorine-38 (Cl 38)    | 10                            |
| Chromium-51 (Cr 51)    | 1,000                         |
| Cobalt-57 (Co 57)      | 100                           |
| Cobalt-58m (Co 58m)    | 10                            |

**Schedule B - Exempt Quantities**

| Radioactive Material        | Exempt Quantity (Microcuries) |
|-----------------------------|-------------------------------|
| Cobalt-58 (Co 58)           | 10                            |
| Cobalt-60 (Co 60)           | 1                             |
| Copper-64 (Cu 64)           | 100                           |
| Dysprosium-165 (Dy 165)     | 10                            |
| Dysprosium-166 (Dy 166)     | 100                           |
| Erbium-169 (Er 169)         | 100                           |
| Erbium-171 (Er 171)         | 100                           |
| Europium-152 (Eu 152) 9.2h  | 100                           |
| Europium-152 (Eu 152) 13 yr | 1                             |
| Europium-154 (Eu 154)       | 1                             |
| Europium-155 (Eu 155)       | 10                            |
| Fluorine-18 (F 18)          | 1,000                         |
| Gadolinium-153 (Gd 153)     | 10                            |
| Gadolinium-159 (Gd 159)     | 100                           |
| Gallium-67 (Ga 67)          | 100                           |
| Gallium-72 (Ga 72)          | 10                            |
| Germanium-68 (Ge 68)        | 10                            |
| Germanium-71 (Ge 71)        | 100                           |
| Gold-195 (Au 195)           | 10                            |
| Gold-198 (Au 198)           | 100                           |
| Gold-199 (Au 199)           | 100                           |
| Hafnium-181 (Hf 181)        | 10                            |
| Holmium-166 (Ho 166)        | 100                           |
| Hydrogen-3 (H 3)            | 1,000                         |
| Indium-111 (In 111)         | 100                           |
| Indium-113m (In 113m)       | 100                           |
| Indium-114m (In 114m)       | 10                            |
| Indium-115m (In 115m)       | 100                           |
| Indium-115 (In 115)         | 10                            |
| Iodine-123 (I 123)          | 100                           |
| Iodine-125 (I 125)          | 1                             |
| Iodine-126 (I 126)          | 1                             |
| Iodine-129 (I 129)          | 0.1                           |
| Iodine-131 (I 131)          | 1                             |
| Iodine-132 (I 132)          | 10                            |
| Iodine-133 (I 133)          | 1                             |
| Iodine-134 (I 134)          | 10                            |
| Iodine-135 (I 135)          | 10                            |
| Iridium-192 (Ir 192)        | 10                            |
| Iridium-194 (Ir 194)        | 100                           |
| Iron-52 (Fe 52)             | 10                            |
| Iron-55 (Fe 55)             | 100                           |
| Iron-59 (Fe 59)             | 10                            |
| Krypton-85 (Kr 85)          | 100                           |
| Krypton-87 (Kr 87)          | 10                            |
| Lanthanum-140 (La 140)      | 10                            |
| Lutetium-177 (Lu 177)       | 100                           |
| Manganese-52 (Mn 52)        | 10                            |
| Manganese-54 (Mn 54)        | 10                            |
| Manganese-56 (Mn 56)        | 10                            |
| Mercury-197m (Hg 197m)      | 100                           |
| Mercury-197 (Hg 197)        | 100                           |
| Mercury-203 (Hg 203)        | 10                            |
| Molybdenum-99 (Mo 99)       | 100                           |

**Schedule B - Exempt Quantities**

| Radioactive Material      | Exempt Quantity (Microcuries) |
|---------------------------|-------------------------------|
| Neodymium-147 (Nd 147)    | 100                           |
| Neodymium-149 (Nd 149)    | 100                           |
| Nickel-59 (Ni 59)         | 100                           |
| Nickel-63 (Ni 63)         | 10                            |
| Nickel-65 (Ni 65)         | 100                           |
| Niobium-93m (Nb 93m)      | 10                            |
| Niobium-95 (Nb 95)        | 10                            |
| Niobium-97 (Nb 97)        | 10                            |
| Osmium-185 (Os 185)       | 10                            |
| Osmium-191m (Os 191m)     | 100                           |
| Osmium-191 (Os 191)       | 100                           |
| Osmium-193 (Os 193)       | 100                           |
| Palladium-103 (Pd 103)    | 100                           |
| Palladium-109 (Pd 109)    | 100                           |
| Phosphorus-32 (P 32)      | 10                            |
| Platinum-191 (Pt 191)     | 100                           |
| Platinum-193m (Pt 193m)   | 100                           |
| Platinum-193 (Pt 193)     | 100                           |
| Platinum-197m (Pt 197m)   | 100                           |
| Platinum-197 (Pt 197)     | 100                           |
| Polonium-210 (Po 210)     | 0.1                           |
| Potassium-42 (K 42)       | 10                            |
| Potassium-43 (K 43)       | 10                            |
| Praseodymium-142 (Pr 142) | 100                           |
| Praseodymium-143 (Pr 143) | 100                           |
| Promethium-147 (Pm 147)   | 10                            |
| Promethium-149 (Pm 149)   | 10                            |
| Rhenium-186 (Re 186)      | 100                           |
| Rhenium-188 (Re 188)      | 100                           |
| Rhodium-103m (Rh 103m)    | 100                           |
| Rhodium-105 (Rh 105)      | 100                           |
| Rubidium-81 (Rb 81)       | 10                            |
| Rubidium-86 (Rb 86)       | 10                            |
| Rubidium-87 (Rb 87)       | 10                            |
| Ruthenium-97 (Ru 97)      | 100                           |
| Ruthenium-103 (Ru 103)    | 10                            |
| Ruthenium-105 (Ru 105)    | 10                            |
| Ruthenium-106 (Ru 106)    | 1                             |
| Samarium-151 (Sm 151)     | 10                            |
| Samarium-153 (Sm 153)     | 100                           |
| Scandium-46 (Sc 46)       | 10                            |
| Scandium-47 (Sc 47)       | 100                           |
| Scandium-48 (Sc 48)       | 10                            |
| Selenium-75 (Se 75)       | 10                            |
| Silicon-31 (Si 31)        | 100                           |
| Silver-105 (Ag 105)       | 10                            |
| Silver-110m (Ag 110m)     | 1                             |
| Silver-111 (Ag 111)       | 100                           |
| Sodium-22 (Na 22)         | 10                            |
| Sodium-24 (Na 24)         | 10                            |
| Strontium-85 (Sr 85)      | 10                            |
| Strontium-89 (Sr 89)      | 1                             |
| Strontium-90 (Sr 90)      | 0.1                           |
| Strontium-91 (Sr 91)      | 10                            |

**Schedule B - Exempt Quantities**

| Radioactive Material   | Exempt Quantity (Microcuries) |
|--|-------------------------------|
| Strontium-92 (Sr 92)   | 10                            |
| Sulphur-35 (S 35)  | 100                           |
| Tantalum-182 (Ta 182)  | 10                            |
| Technetium-96 (Tc 96)  | 10                            |
| Technetium-97m (Tc 97m)  | 100                           |
| Technetium-97 (Tc 97)  | 100                           |
| Technetium-99m (Tc 99m)  | 100                           |
| Technetium-99 (Tc 99)  | 10                            |
| Tellurium-125m (Te 125m)   | 10                            |
| Tellurium-127m (Te 127m)   | 10                            |
| Tellurium-127 (Te 127)   | 100                           |
| Tellurium-129m (Te 129m)   | 10                            |
| Tellurium-129 (Te 129)   | 100                           |
| Tellurium-131m (Te 131m)   | 10                            |
| Tellurium-132 (Te 132)   | 10                            |
| Terbium-160 (Tb 160)   | 10                            |
| Thallium-200 (Tl 200)  | 100                           |
| Thallium-201 (Tl 201)  | 100                           |
| Thallium-202 (Tl 202)  | 100                           |
| Thallium-204 (Tl 204)  | 10                            |
| Thulium-170 (Tm 170)   | 10                            |
| Thulium-171 (Tm 171)   | 10                            |
| Tin 113-(Sn 113)   | 10                            |
| Tin 125-(Sn 125)   | 10                            |
| Tungsten-181 (W 181)   | 10                            |
| Tungsten-185 (W 185)   | 10                            |
| Tungsten-187 (W 187)   | 100                           |
| Vanadium-48 (V 48)   | 10                            |
| Xenon-131m (Xe 131m)   | 1,000                         |
| Xenon-133 (Xe 133)   | 100                           |
| Xenon-135 (Xe 135)   | 100                           |
| Ytterbium-175 (Yb 175)   | 100                           |
| Yttrium-87 (Y 87)  | 10                            |
| Yttrium-88 (Y 88)  | 10                            |
| Yttrium-90 (Y 90)  | 10                            |
| Yttrium-91 (Y 91)  | 10                            |
| Yttrium-92 (Y 92)  | 100                           |
| Yttrium-93 (Y 93)  | 100                           |
| Zinc-65 (Zn 65)  | 10                            |
| Zinc-69m (Zn 69m)  | 100                           |
| Zinc-69 (Zn 69)  | 1,000                         |
| Zirconium-93 (Zr 93)   | 10                            |
| Zirconium-95 (Zr 95)   | 10                            |
| Zirconium-97 (Zr 97)   | 10                            |
| Any radioactive material not listed above other than alpha-emitting radioactive material | 0.1                           |

(c) Schedule C.

**SCHEDULE C  
LIMITS FOR BROAD LICENSES****Schedule C - Limits For Broad Licenses**

| Radioactive Materials | Column I (Curies) | Column II (Curies) |
|-----------------------|-------------------|--------------------|
|-----------------------|-------------------|--------------------|

**Schedule C - Limits For Broad Licenses**

| Radioactive Materials       | Column I (Curies) | Column II (Curies) |
|-----------------------------|-------------------|--------------------|
| Antimony-122 (Sb 122)       | 1                 | 0.01               |
| Antimony-124 (Sb 124)       | 1                 | 0.01               |
| Antimony-125 (Sb 125)       | 1                 | 0.01               |
| Arsenic-73 (As 73)          | 10                | 0.1                |
| Arsenic-74 (As 74)          | 1                 | 0.01               |
| Arsenic-76 (As 76)          | 1                 | 0.01               |
| Arsenic-77 (As 77)          | 10                | 0.1                |
| Barium-131 (Ba 131)         | 10                | 0.1                |
| Barium-140 (Ba 140)         | 1                 | 0.01               |
| Beryllium-7 (Be 7)          | 10                | 0.1                |
| Bismuth-210 (Bi 210)        | 0.1               | 0.001              |
| Bromine-82 (Br 82)          | 10                | 0.1                |
| Cadmium-109 (Cd 109)        | 1                 | 0.01               |
| Cadmium-115m (Cd 115m)      | 1                 | 0.01               |
| Cadmium-115 (Cd 115)        | 10                | 0.1                |
| Calcium-45 (Ca 45)          | 1                 | 0.01               |
| Calcium-47 (Ca 47)          | 10                | 0.1                |
| Carbon-14 (C 14)            | 100               | 1.0                |
| Cerium-141 (Ce 141)         | 10                | 0.1                |
| Cerium-143 (Ce 143)         | 10                | 0.1                |
| Cerium-144 (Ce 144)         | 0.1               | 0.001              |
| Cesium-131 (Cs 131)         | 100               | 1.0                |
| Cesium-134m (Cs 134m)       | 100               | 1.0                |
| Cesium-134 (Cs 134)         | 0.1               | 0.001              |
| Cesium-135 (Cs 135)         | 1                 | 0.01               |
| Cesium-136 (Cs 136)         | 10                | 0.1                |
| Cesium-137 (Cs 137)         | 0.1               | 0.001              |
| Chlorine-36 (Cl 36)         | 0.01              | 0.001              |
| Chlorine-38 (Cl 38)         | 100               | 1.0                |
| Chromium-51 (Cr 51)         | 100               | 1.0                |
| Cobalt-57 (Co 57)           | 10                | 0.1                |
| Cobalt-58m (Co 58m)         | 100               | 1.0                |
| Cobalt-58 (Co 58)           | 1                 | 0.01               |
| Cobalt-60 (Co 60)           | 0.1               | 0.001              |
| Copper-64 (Cu 64)           | 10                | 0.1                |
| Dysprosium-165 (Dy 165)     | 100               | 1.0                |
| Dysprosium-166 (Dy 166)     | 10                | 0.1                |
| Erbium-169 (Er 169)         | 10                | 0.1                |
| Erbium-171 (Er 171)         | 10                | 0.1                |
| Europium-152 (Eu 152) 9.2h  | 10                | 0.1                |
| Europium-152 (Eu 152) 13 yr | 0.1               | 0.001              |
| Europium-154 (Eu 154)       | 0.1               | 0.001              |
| Europium-155 (Eu 155)       | 1                 | 0.01               |
| Fluorine-18 (F 18)          | 100               | 1.0                |
| Gadolinium-153 (Gd 153)     | 1                 | 0.01               |
| Gadolinium-159 (Gd 159)     | 10                | 0.1                |
| Gallium-72 (Ga 72)          | 10                | 0.1                |
| Germanium-71 (Ge 71)        | 100               | 1.0                |
| Gold-198 (Au 198)           | 10                | 0.1                |
| Gold-199 (Au 199)           | 10                | 0.1                |
| Hafnium-181 (Hf 181)        | 1                 | 0.01               |
| Holmium-166 (Ho 166)        | 10                | 0.1                |
| Hydrogen-3 (H 3)            | 100               | 1.0                |
| Indium-113m (In 113m)       | 100               | 1.0                |

**Schedule C - Limits For Broad Licenses**

| Radioactive Materials     | Column I (Curies) | Column II (Curies) |
|---------------------------|-------------------|--------------------|
| Indium-114m (In 114m)     | 1                 | 0.01               |
| Indium-115m (In 115m)     | 100               | 1.0                |
| Indium-115 (In 115)       | 1                 | 0.01               |
| Iodine-125 (I 125)        | 0.1               | 0.001              |
| Iodine-126 (I 126)        | 0.1               | 0.001              |
| Iodine-129 (I 129)        | 0.1               | 0.001              |
| Iodine-131 (I 131)        | 0.1               | 0.001              |
| Iodine-132 (I 132)        | 10                | 0.1                |
| Iodine-133 (I 133)        | 1                 | 0.01               |
| Iodine-134 (I 134)        | 10                | 0.1                |
| Iodine-135 (I 135)        | 1                 | 0.01               |
| Iridium-192 (Ir 192)      | 1                 | 0.01               |
| Iridium-194 (Ir 194)      | 10                | 0.1                |
| Iron-55 (Fe 55)           | 10                | 0.1                |
| Iron-59 (Fe 59)           | 1                 | 0.01               |
| Krypton-85 (Kr 85)        | 100               | 1.0                |
| Krypton-87 (Kr 87)        | 10                | 0.1                |
| Lanthanum-140 (La 140)    | 1                 | 0.01               |
| Lutetium-177 (Lu 177)     | 10                | 0.1                |
| Manganese-52 (Mn 52)      | 1                 | 0.01               |
| Manganese-54 (Mn 54)      | 1                 | 0.01               |
| Manganese-56 (Mn 56)      | 10                | 0.1                |
| Mercury-197m (Hg 197m)    | 10                | 0.1                |
| Mercury-197 (Hg 197)      | 10                | 0.1                |
| Mercury-203 (Hg 203)      | 1                 | 0.01               |
| Molybdenum-99 (Mo 99)     | 10                | 0.1                |
| Neodymium-147 (Nd 147)    | 10                | 0.1                |
| Neodymium-149 (Nd 149)    | 10                | 0.1                |
| Nickel-59 (Ni 59)         | 10                | 0.1                |
| Nickel-63 (Ni 63)         | 1                 | 0.01               |
| Nickel-65 (Ni 65)         | 10                | 0.1                |
| Niobium-93m (Nb 93m)      | 1                 | 0.01               |
| Niobium-95 (Nb 95)        | 1                 | 0.01               |
| Niobium-97 (Nb 97)        | 100               | 1.0                |
| Osmium-185 (Os 185)       | 1                 | 0.01               |
| Osmium-191m (Os 191m)     | 100               | 1.0                |
| Osmium-191 (Os 191)       | 10                | 0.1                |
| Osmium-193 (Os 193)       | 10                | 0.1                |
| Palladium-103 (Pd 103)    | 10                | 0.1                |
| Palladium-109 (Pd 109)    | 10                | 0.1                |
| Phosphorus-32 (P 32)      | 1                 | 0.01               |
| Platinum-191 (Pt 191)     | 10                | 0.1                |
| Platinum-193m (Pt 193m)   | 100               | 1.0                |
| Platinum-193 (Pt 193)     | 10                | 0.1                |
| Platinum-197m (Pt 197m)   | 100               | 1.0                |
| Platinum-197 (Pt 197)     | 10                | 0.1                |
| Polonium-210 (Po 210)     | 0.01              | 0.0001             |
| Potassium-42 (K 42)       | 1                 | 0.01               |
| Praseodymium-142 (Pr 142) | 10                | 0.1                |
| Praseodymium-143 (Pr 143) | 10                | 0.1                |
| Promethium-147 (Pm 147)   | 1                 | 0.01               |
| Promethium-149 (Pm 149)   | 10                | 0.1                |
| Radium-226                | 0.01              | 0.0001             |
| Rhenium-186 (Re 186)      | 10                | 0.1                |

**Schedule C - Limits For Broad Licenses**

| Radioactive Materials    | Column I (Curies) | Column II (Curies) |
|--------------------------|-------------------|--------------------|
| Rhenium-188 (Re 188)     | 10                | 0.1                |
| Rhodium-103m (Rh 103m)   | 1,000             | 0                  |
| Rhodium-105 (Rh 105)     | 10                | 0.1                |
| Rubidium-86 (Rb 86)      | 1                 | 0.01               |
| Rubidium-87 (Rb 87)      | 1                 | 0.01               |
| Ruthenium-97 (Ru 97)     | 100               | 1.0                |
| Ruthenium-103 (Ru 103)   | 1                 | 0.01               |
| Ruthenium-105 (Ru 105)   | 10                | 0.1                |
| Ruthenium-106 (Ru 106)   | 0.1               | 0.001              |
| Samarium-151 (Sm 151)    | 1                 | 0.01               |
| Samarium-153 (Sm 153)    | 10                | 0.1                |
| Scandium-46 (Sc 46)      | 1                 | 0.01               |
| Scandium-47 (Sc 47)      | 10                | 0.1                |
| Scandium-48 (Sc 48)      | 1                 | 0.01               |
| Selenium-75 (Se 75)      | 1                 | 0.01               |
| Silicon-31 (Si 31)       | 10                | 0.1                |
| Silver-105 (Ag 105)      | 1                 | 0.01               |
| Silver- 110m (Ag 110m)   | 0.1               | 0.001              |
| Silver-111 (Ag 111)      | 10                | 0.1                |
| Sodium-22 (Na 22)        | 0.1               | 0.001              |
| Sodium-24 (Na 24)        | 1                 | 0.01               |
| Strontium-85m (Sr 85m)   | 1,000             | 10.0               |
| Strontium-85 (Sr 85)     | 1                 | 0.01               |
| Strontium-89 (Sr 89)     | 1                 | 0.01               |
| Strontium-90 (Sr 90)     | 0.01              | 0.0001             |
| Strontium-91 (Sr 91)     | 10                | 0.1                |
| Strontium-92 (Sr 92)     | 10                | 0.1                |
| Sulphur-35 (S 35)        | 10                | 0.1                |
| Tantalum-182 (Ta 182)    | 1                 | 0.01               |
| Technetium-96 (Tc 96)    | 10                | 0.1                |
| Technetium-97m (Tc 97m)  | 10                | 0.1                |
| Technetium-97 (Tc 97)    | 10                | 0.1                |
| Technetium-99m (Tc 99m)  | 100               | 1.0                |
| Technetium-99 (Tc 99)    | 1                 | 0.01               |
| Tellurium-125m (Te 125m) | 1                 | 0.01               |
| Tellurium-127m (Te 127m) | 1                 | 0.01               |
| Tellurium-127 (Te 127)   | 10                | 0.1                |
| Tellurium-129m (Te 129m) | 1                 | 0.01               |
| Tellurium-129 (Te 129)   | 100               | 1.0                |
| Tellurium-131m (Te 131m) | 10                | 0.1                |
| Tellurium-132 (Te 132)   | 1                 | 0.01               |
| Terbium-160 (Tb 160)     | 1                 | 0.01               |
| Thallium-200 (Tl 200)    | 10                | 0.1                |
| Thallium-201 (Tl 201)    | 10                | 0.1                |
| Thallium-202 (Tl 202)    | 10                | 0.1                |
| Thallium-204 (Tl 204)    | 1                 | 0.01               |
| Thulium-170 (Tm 170)     | 1                 | 0.01               |
| Thulium-171 (Tm 171)     | 1                 | 0.01               |
| Tin 113-(Sn 113)         | 1                 | 0.01               |
| Tin 125-(Sn 125)         | 1                 | 0.01               |
| Tungsten-181 (W 181)     | 1                 | 0.01               |
| Tungsten-185 (W 185)     | 1                 | 0.01               |
| Tungsten-187 (W 187)     | 10                | 0.1                |
| Vanadium-48 (V 48)       | 1                 | 0.01               |

**Schedule C - Limits For Broad Licenses**

| Radioactive Materials   | Column I (Curies) | Column II (Curies) |
|---|-------------------|--------------------|
| Xenon-131m (Xe 131m)  | 1,000             | 0                  |
| Xenon-133 (Xe 133)  | 100               | 1.0                |
| Xenon-135 (Xe 135)  | 100               | 1.0                |
| Ytterbium-175 (Yb 175)  | 10                | 0.1                |
| Yttrium-90 (Y 90)   | 1                 | 0.1                |
| Yttrium-91 (Y 91)   | 1                 | 0.1                |
| Yttrium-92 (Y 92)   | 10                | 0.1                |
| Yttrium-93 (Y 93)   | 1                 | 0.01               |
| Zinc-65 (Zn 65)   | 1                 | 0.01               |
| Zinc-69m (Zn 69m)   | 10                | 0.1                |
| Zinc-69 (Zn 69)   | 100               | 1.0                |
| Zirconium-93 (Zr 93)  | 1                 | 0.01               |
| Zirconium-95 (Zr 95)  | 1                 | 0.01               |
| Zirconium-97 (Zr 97)  | 1                 | 0.01               |
| Any radioactive material other than source material, or alpha-emitting radioactive material not listed above. | 0.1               | 0.001              |

(d) Schedule D. Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

1. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This schedule establishes criteria for passing the financial test and for obtaining the parent company guarantee.

2. Financial Test. To pass the financial test, the parent company must meet the criteria of either (21)(d)2.(i) or (21)(d)2.(ii) as follows:

(i) The parent company must have:

(I) two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(II) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used);

(III) Tangible net worth of at least \$10 million; and

(IV) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(ii) The parent company must have:

(I) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's;

(II) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(III) Tangible net worth of at least \$10 million; and

(IV) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

(iii) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently-audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Director and Division within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(iv) After the initial financial test, the parent company must repeat the passage of the test within 120 days after the close of each succeeding fiscal year. If the parent company no longer meets the requirements, as appropriate, of either (21)(d)2.(i) or (21)(d)2.(ii), the licensee must send notice to the Director and Division of intent to establish alternate financial assurance as specified in the Division's Rules. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

3. Parent Company Guarantee. The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

(i) The parent company guarantee shall remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Director and Division. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Director, as evidenced by the return receipts;

(ii) If the licensee fails to provide alternate financial assurance as specified in the Division's Rules within 90 days after receipt by the licensee and the Director and Division of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor shall provide such alternative financial assurance in the name of the licensee;

(iii) The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license; and

(iv) If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(e) Schedule E.

## **SCHEDULE E**

### **QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE**

#### **Schedule E - Emergency Plan For Responding to a Release**

| <b>Radioactive Material <sup>(1)</sup></b> | <b>Release Fraction</b> | <b>Quantity (Curies)</b> |
|--|-------------------------|--------------------------|
| Actinium-228                               | 0.001                   | 4,000                    |
| Americium-241                              | 0.001                   | 2                        |
| Americium-242                              | 0.001                   | 2                        |
| Americium-243                              | 0.001                   | 2                        |
| Antimony-124                               | 0.01                    | 4,000                    |
| Antimony-126                               | 0.01                    | 6,000                    |
| Barium-133                                 | 0.01                    | 10,000                   |
| Barium-140                                 | 0.01                    | 30,000                   |
| Bismuth-207                                | 0.01                    | 5,000                    |

**Schedule E - Emergency Plan For Responding to a Release**

| Radioactive Material <sup>(1)</sup> | Release Fraction | Quantity (Curies) |
|-------------------------------------|------------------|-------------------|
| Bismuth-210                         | 0.01             | 600               |
| Cadmium-109                         | 0.01             | 1,000             |
| Cadmium-113                         | 0.01             | 80                |
| Calcium-45                          | 0.01             | 20,000            |
| Californium-252                     | 0.001            | 9 (20 mg)         |
| Carbon-14 (Non Carbon dioxide)      | 0.01             | 50,000            |
| Cerium-141                          | 0.01             | 10,000            |
| Cerium-144                          | 0.01             | 300               |
| Cesium-134                          | 0.01             | 2,000             |
| Cesium-137                          | 0.01             | 3,000             |
| Chlorine-36                         | 0.5              | 100               |
| Chromium-51                         | 0.01             | 300,000           |
| Cobalt-60                           | 0.001            | 5,000             |
| Copper-64                           | 0.01             | 200,000           |
| Curium-242                          | 0.001            | 60                |
| Curium-243                          | 0.001            | 3                 |
| Curium-244                          | 0.001            | 4                 |
| Curium-245                          | 0.001            | 2                 |
| Europium-152                        | 0.01             | 500               |
| Europium-154                        | 0.01             | 400               |
| Europium-155                        | 0.01             | 3,000             |
| Germanium-68                        | 0.01             | 2,000             |
| Gadolinium-153                      | 0.01             | 5,000             |
| Gold-198                            | 0.01             | 30,000            |
| Hafnium-172                         | 0.01             | 400               |
| Hafnium-181                         | 0.01             | 7,000             |
| Holmium-166m                        | 0.01             | 100               |
| Hydrogen-3                          | 0.5              | 20,000            |
| Iodine-125                          | 0.5              | 10                |
| Iodine-131                          | 0.5              | 10                |
| Indium-114m                         | 0.01             | 1,000             |
| Iridium-192                         | 0.001            | 40,000            |
| Iron-55                             | 0.01             | 40,000            |
| Iron-59                             | 0.01             | 7,000             |
| Krypton-85                          | 1.0              | 6,000,000         |
| Lead-210                            | 0.01             | 8                 |
| Manganese-56                        | 0.01             | 60,000            |
| Mercury-203                         | 0.01             | 10,000            |
| Molybdenum-99                       | 0.01             | 30,000            |
| Neptunium-237                       | 0.001            | 2                 |
| Nickel-63                           | 0.01             | 20,000            |
| Niobium-94                          | 0.01             | 300               |
| Phosphorus-32                       | 0.5              | 100               |
| Phosphorus-33                       | 0.5              | 1,000             |
| Polonium-210                        | 0.01             | 10                |
| Potassium-42                        | 0.01             | 9,000             |
| Promethium-145                      | 0.01             | 4,000             |
| Promethium-147                      | 0.01             | 4,000             |
| Radium-226                          | 0.001            | 100               |
| Ruthenium-106                       | 0.01             | 200               |
| Samarium-151                        | 0.01             | 4,000             |
| Scandium-46                         | 0.01             | 3,000             |
| Selenium-75                         | 0.01             | 10,000            |
| Silver-110m                         | 0.01             | 1,000             |

**Schedule E - Emergency Plan For Responding to a Release**

| Radioactive Material <sup>(1)</sup>                           | Release Fraction | Quantity (Curies) |
|---|------------------|-------------------|
| Sodium-22   | 0.01             | 9,000             |
| Sodium-24   | 0.01             | 10,000            |
| Strontium-89  | 0.01             | 3,000             |
| Strontium-90  | 0.01             | 90                |
| Sulfur-35   | 0.5              | 900               |
| Technetium-99   | 0.01             | 10,000            |
| Technetium-99m  | 0.01             | 400,000           |
| Tellurium-127m  | 0.01             | 5,000             |
| Tellurium-129m  | 0.01             | 5,000             |
| Terbium-160   | 0.01             | 4,000             |
| Thulium-170   | 0.01             | 4,000             |
| Tin-13  | 0.01             | 10,000            |
| Tin-123   | 0.01             | 3,000             |
| Tin-126   | 0.01             | 1,000             |
| Titanium-44   | 0.01             | 100               |
| Vanadium-48   | 0.01             | 7,000             |
| Xenon-133   | 1.0              | 900,000           |
| Yttrium-91  | 0.01             | 2,000             |
| Zinc-65   | 0.01             | 5,000             |
| Zirconium-93  | 0.01             | 400               |
| Zirconium-95  | 0.01             | 5,000             |
| Any other beta-/gamma-emitter                                 | 0.01             | 10,000            |
| Mixed fission products  | 0.01             | 1,000             |
| Mixed Corrosion Products                                      | 0.01             | 10,000            |
| Contaminated equipment, beta/gamma                            | 0.001            | 10,000            |
| Irradiated material, any form other than solid noncombustible | 0.01             | 1,000             |
| Irradiated material, solid noncombustible                     | 0.001            | 10,000            |
| Mixed radioactive waste, beta/gamma                           | 0.01             | 1,000             |
| Packaged mixed waste, beta/gamma <sup>2</sup>                 | 0.001            | 10,000            |
| Any other alpha-emitter                                       | 0.001            | 2                 |
| Contaminated equipment, alpha                                 | 0.0001           | 20                |
| Packaged waste, alpha <sup>(2)</sup>                          | 0.0001           | 20                |

*Footnotes:*

*(1) For combinations of radioactive materials listed above, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule E exceeds one.*

*(2) Waste packaged in Type B containers does not require an emergency plan.*

(f) Schedule F

**SCHEDULE F  
QUANTITIES FOR USE WITH DECOMMISSIONING**

**Schedule F - Quantities for Use With Decommissioning**

| Radioactive Material | Quantity (Microcurie <sup>(a)</sup> ) |
|----------------------|---------------------------------------|
| Americium-241        | 0.01                                  |
| Antimony-122         | 100                                   |
| Antimony-124         | 10                                    |
| Antimony-125         | 10                                    |

**Schedule F - Quantities for Use With Decommissioning**

| Radioactive Material | Quantity (Microcurie <sup>(a)</sup> ) |
|----------------------|---------------------------------------|
| Arsenic-73           | 100                                   |
| Arsenic-74           | 10                                    |
| Arsenic-76           | 10                                    |
| Arsenic-77           | 100                                   |
| Barium-131           | 10                                    |
| Barium-133           | 10                                    |
| Barium-140           | 10                                    |
| Bismuth-210          | 1                                     |
| Bromine-82           | 10                                    |
| Cadmium-109          | 10                                    |
| Cadmium-115m         | 10                                    |
| Cadmium-115          | 100                                   |
| Calcium-45           | 10                                    |
| Calcium-47           | 10                                    |
| Carbon-14            | 100                                   |
| Cerium-141           | 100                                   |
| Cerium-143           | 100                                   |
| Cerium-144           | 1                                     |
| Cesium-131           | 1,000                                 |
| Cesium-134m          | 100                                   |
| Cesium-134           | 1                                     |
| Cesium-135           | 10                                    |
| Cesium-136           | 10                                    |
| Cesium-137           | 10                                    |
| Chlorine-36          | 10                                    |
| Chlorine-38          | 10                                    |
| Chromium-51          | 1,000                                 |
| Cobalt-58m           | 10                                    |
| Cobalt-58            | 10                                    |
| Cobalt-60            | 1                                     |
| Copper-64            | 100                                   |
| Dysprosium-165       | 10                                    |
| Dysprosium-166       | 100                                   |
| Erbium-169           | 100                                   |
| Erbium-171           | 100                                   |
| Europium-152 (9.2 h) | 100                                   |
| Europium-152 (13 yr) | 1                                     |
| Europium-154         | 1                                     |
| Europium-155         | 10                                    |
| Fluorine-18          | 1,000                                 |
| Gadolinium-153       | 10                                    |
| Gadolinium-159       | 100                                   |
| Gallium-72           | 10                                    |
| Germanium-71         | 0                                     |
| Hafnium-181          | 10                                    |
| Holmium-166          | 100                                   |
| Hydrogen-3           | 1,000                                 |
| Indium-113m          | 100                                   |
| Indium-114m          | 10                                    |
| Indium-115m          | 100                                   |
| Indium-115           | 10                                    |
| Iodine-125           | 1                                     |
| Iodine-126           | 1                                     |
| Iodine-129           | 0.1                                   |

**Schedule F - Quantities for Use With Decommissioning**

| Radioactive Material | Quantity (Microcurie <sup>(a)</sup> ) |
|----------------------|---------------------------------------|
| Iodine-131           | 1                                     |
| Iodine-132           | 10                                    |
| Iodine-133           | 1                                     |
| Iodine-134           | 10                                    |
| Iodine-135           | 10                                    |
| Iridium-192          | 10                                    |
| Iridium-194          | 100                                   |
| Iron-55              | 100                                   |
| Iron-59              | 10                                    |
| Krypton-85           | 100                                   |
| Krypton-87           | 10                                    |
| Lanthanum-140        | 10                                    |
| Lutetium-177         | 100                                   |
| Manganese-52         | 10                                    |
| Manganese-54         | 10                                    |
| Manganese-56         | 10                                    |
| Mercury-197m         | 100                                   |
| Mercury-197          | 100                                   |
| Mercury-203          | 10                                    |
| Molybdenum-99        | 100                                   |
| Neodymium-147        | 100                                   |
| Neodymium-149        | 100                                   |
| Nickel-59            | 100                                   |
| Nickel-63            | 10                                    |
| Nickel-65            | 100                                   |
| Niobium-93m          | 10                                    |
| Niobium-95           | 10                                    |
| Niobium-97           | 10                                    |
| Osmium-185           | 10                                    |
| Osmium-191m          | 100                                   |
| Osmium-191           | 100                                   |
| Osmium-193           | 100                                   |
| Palladium-103        | 100                                   |
| Palladium-109        | 100                                   |
| Phosphorus-32        | 10                                    |
| Platinum-191         | 100                                   |
| Platinum-193m        | 100                                   |
| Platinum-193         | 100                                   |
| Platinum-197m        | 100                                   |
| Platinum-197         | 100                                   |
| Plutonium-239        | 0.01                                  |
| Polonium-210         | 0.1                                   |
| Potassium-42         | 10                                    |
| Praseodymium-142     | 100                                   |
| Praseodymium-143     | 100                                   |
| Promethium-147       | 10                                    |
| Promethium-149       | 10                                    |
| Radium-226           | 0.01                                  |
| Rhenium-186          | 100                                   |
| Rhenium-188          | 100                                   |
| Rhodium-103m         | 100                                   |
| Rhodium-105          | 100                                   |
| Rubidium-86          | 10                                    |
| Rubidium-87          | 10                                    |

**Schedule F - Quantities for Use With Decommissioning**

| Radioactive Material            | Quantity (Microcurie <sup>(a)</sup> ) |
|---------------------------------|---------------------------------------|
| Ruthenium-97                    | 100                                   |
| Ruthenium-103                   | 10                                    |
| Ruthenium-105                   | 10                                    |
| Ruthenium-106                   | 1                                     |
| Samarium-151                    | 10                                    |
| Samarium-153                    | 100                                   |
| Scandium-46                     | 10                                    |
| Scandium-47                     | 100                                   |
| Scandium-48                     | 10                                    |
| Selenium-75                     | 10                                    |
| Silicon-31                      | 100                                   |
| Silver-105                      | 10                                    |
| Silver-110m                     | 1                                     |
| Silver-111                      | 100                                   |
| Sodium-22                       | 1                                     |
| Sodium-24                       | 10                                    |
| Strontium-85                    | 10                                    |
| Strontium-89                    | 1                                     |
| Strontium-90                    | 0.1                                   |
| Strontium-91                    | 10                                    |
| Strontium-92                    | 10                                    |
| Sulfur-35                       | 100                                   |
| Tantalum-182                    | 10                                    |
| Technetium-96                   | 10                                    |
| Technetium-97m                  | 100                                   |
| Technetium-97                   | 100                                   |
| Technetium-99m                  | 100                                   |
| Technetium-99                   | 10                                    |
| Tellurium-125m                  | 10                                    |
| Tellurium-127m                  | 10                                    |
| Tellurium-127                   | 100                                   |
| Tellurium-129m                  | 10                                    |
| Tellurium-129                   | 100                                   |
| Tellurium-131m                  | 10                                    |
| Tellurium-132                   | 10                                    |
| Terbium-160                     | 10                                    |
| Thallium-200                    | 100                                   |
| Thallium-201                    | 100                                   |
| Thallium-202                    | 100                                   |
| Thallium-204                    | 10                                    |
| Thorium (natural) <sup>b/</sup> | 100                                   |
| Thulium-170                     | 10                                    |
| Thulium-171                     | 10                                    |
| Tin-113                         | 10                                    |
| Tin-125                         | 10                                    |
| Tungsten-181                    | 10                                    |
| Tungsten-185                    | 10                                    |
| Tungsten-187                    | 100                                   |
| Uranium (natural) <sup>c/</sup> | 100                                   |
| Uranium-233                     | 0.01                                  |
| Uranium-234                     | 0.01                                  |
| Uranium-235                     | 0.01                                  |
| Vanadium-48                     | 10                                    |
| Xenon-131m                      | 1,000                                 |

## Schedule F - Quantities for Use With Decommissioning

| Radioactive Material | Quantity (Microcurie <sup>(a)</sup> ) |
|----------------------|---------------------------------------|
| Xenon-133            | 100                                   |
| Xenon-135            | 100                                   |
| Ytterbium-175        | 100                                   |
| Yttrium-90           | 10                                    |
| Yttrium-91           | 10                                    |
| Yttrium-92           | 100                                   |
| Yttrium-93           | 100                                   |
| Zinc-65              | 10                                    |
| Zinc-69m             | 100                                   |
| Zinc-69              | 1,000                                 |
| Zirconium-93         | 10                                    |
| Zirconium-95         | 10                                    |
| Zirconium-97         | 10                                    |

Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition. 0.01

Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition. 0.10

<sup>a/</sup> To convert  $\mu\text{Ci}$  to  $\text{kBq}$ , multiply the  $\mu\text{Ci}$  value by 37.

<sup>b/</sup> Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

<sup>c/</sup> Based on alpha disintegration rate of U-238, U-234, and U-235.

(g) Schedule G. Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.

### 1. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of (21)(g)2. The terms of the self-guarantee are in (21)(g)3. This schedule establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

### 2. Financial Test

(i) To pass the financial test, a company must meet all of the following criteria:

(I) Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee.

(II) Assets located in the United States amounting to at least 90 percent of total decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee.

(III) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

(ii) To pass the financial test, a company must meet all of the following additional requirements:

(I) The company must have at least one class of equity securities registered under the Security Exchange Act of 1934.

(II) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Director and Division within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(III) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(iii) If the licensee no longer meets the requirements of (21)(g)2.(i), the licensee must send immediate notice to the Director and Division of its intent to establish alternate financial assurance as specified in the Division's Rules within 120 days of such notice.

### 3. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(i) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Director and Division. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Director, as evidenced by the return receipt.

(ii) The licensee shall provide alternative financial assurance as specified in the Division's Rules within 90 days following receipt by the Director of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions must remain in effect until the Director has terminated the license or until another financial assurance method acceptable to the Director has been put in effect by the licensee.

(iv) The licensee will promptly forward to the Department, the Division and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Director and Division within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of (21)(g)2.(i).

(vi) The applicant or licensee must provide to the Director and Division a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Director, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(h) Schedule H. Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals.

#### 1. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of (h)2. The terms of the self-guarantee are in (h)3. This schedule establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

#### 2. Financial Test

(i) For colleges and universities, to pass the financial test a college or university must meet either the criteria in (h)2.(i)(I) or the criteria in (h)2.(i)(II).

(I) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(II) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(ii) For hospitals, to pass the financial test a hospital must meet either the criteria in (h)2.(ii)(I) or the criteria in (h)2.(ii)(II):

(I) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(II) For applicants or licensees that do not issue bonds, all the following tests must be met:

I. (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

II. Long term debt divided by net fixed assets must be less than or equal to 0.67.

III. (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

IV. Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

(iii) In addition, to pass the financial test, a licensee must meet all the following requirements:

(I) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Director and Division within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(II) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(III) If the licensee no longer meets the requirements of (h)1., the licensee must send notice to the Director and Division of its intent to establish alternative financial assurance as specified in Division's Rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

### 3. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(i) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Director and Division. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(ii) The licensee shall provide alternative financial assurance as specified in the Division's Rules within 90 days following receipt by the Director of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions must remain in effect until the Director has terminated the license or until another financial assurance method acceptable to the Director has been put in effect by the licensee.

(iv) The applicant or licensee must provide to the Director and Division a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Director, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the Director and Division within 20 days after publication of the change by the rating service.

**AUTHORITY:** O.C.G.A. § [31-13-1](#) et seq., as amended.

**HISTORY:** Original Rule entitled "Licensing of Radioactive Material" adopted. F. May 2, 1991; eff. May 22, 1991.

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**Amended:** F. Feb. 26, 2020; eff. Mar. 17, 2020.

### **391-3-17-.05 Use of Radionuclides in the Healing Arts**

(1) **Purpose and Scope.** This Rule, 391-3-17-.05, establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients,

and human research subjects. The requirements and provisions of this Rule are in addition to, and not in substitution for, others in these regulations unless specifically exempted. All numbered and lettered references within this Rule refer to parts of this Rule, unless stated otherwise.

**(2) Definitions.**

(a) "Accredited institution," means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

(b) "Address of use," means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

(c) "Area of use," means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

(d) "Authorized medical physicist," means an individual who:

1. Meets the requirements in Rules .05(23)(a) and .05(27); or
2. Is identified as an authorized medical physicist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State; or
3. Is identified as an authorized medical physicist on a permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(e) "Authorized nuclear pharmacist," means a pharmacist who:

1. Meets the requirements in Rules .05(24)(a) and .05(27); or
2. Is identified as an authorized nuclear pharmacist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State; or
3. Is identified as an authorized nuclear pharmacist on a permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(f) "Authorized user," means a physician, dentist, or podiatrist who:

1. Meets the requirements in Rule .05(27) and .05(43)(a), .05(47)(a), .05(52)(a), .05(53)(a), .05(54)(a), .05(63)(a), .05(66)(a), or .05(84)(a); or
2. Is identified as an authorized user on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State; or
3. Is identified as an authorized user on a permit issued by the Director, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

(g) "Brachytherapy," means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

(h) "Brachytherapy source," means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

- (i) "Client's address," means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with Rule .05(38).
- (j) "Dedicated check source," means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.
- (k) "Dentist," means an individual licensed to engage in the practice dentistry under the Authority of O.C.G.A. [43-11-40](#).
- (l) "Diagnostic clinical procedures manual," means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radio pharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.
- (m) "High dose-rate remote after loader," (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rad) per hour at the treatment site.
- (n) "Low dose-rate remote after loader," (LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rad) per hour at the treatment site.
- (o) "Management," means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.
- (p) "Manual brachytherapy," means a type of therapy in which brachytherapy sources are manually applied or inserted.
- (q) "Medical institution," means an organization in which several medical disciplines are practiced.
- (r) "Medical use," means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.
- (s) "Medium dose-rate remote afterloader," (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rad), but less than, or equal to, 12 gray (1200 rad) per hour at the treatment site.
- (t) "Misadministration," means an event that meets the criteria in Rule .05(115)(a).
- (u) "Mobile medical service," means the transportation of radioactive material or its medical use at the client's address.
- (v) "Nuclear medicine technologist," means an individual who meets the requirements of Rule .05(25)(a) and, is under the supervision of an authorized user, to prepare or administers radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.
- (w) "Nuclear medicine technology," means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.
- (x) "Output," means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.
- (y) "Patient intervention," means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.
- (z) "Pharmacist," means any individual who is licensed to practice Pharmacy in this State by the Georgia State Board of Pharmacy.

(aa) "Physician," means any person who is licensed to engage in the practice of medicine under the Authority of O.C.G.A. [43-34-20](#) or the limited practice of medicine under O.C.G.A. [43-35-1](#).

(bb) "Podiatrist," means an individual licensed by the appropriate authority to practice podiatry in the state of Georgia.

(cc) "Positron Emission Tomography (PET) radionuclide production facility" is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(dd) "Preceptor," means an individual who provides, directs or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, an Associate Radiation Safety Officer or a Radiation Safety Officer.

(ee) "Prescribed dosage," means the specified activity or range of activity of radioactive drug as documented:

1. In a written directive; or
2. In accordance with the directions of the authorized user for procedures performed pursuant to Rule .05(41), (44) and (48).

(ff) "Prescribed dose," means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive;
3. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(gg) "Pulsed dose-rate remote afterloader," (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(hh) "Radiation Safety Officer," means an individual who:

1. Meets the requirements in Rule .05(22)(a) or .05(22)(c)1. And .05(27); or
2. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Division for similar types and uses of radioactive material.

(ii) "Radiation therapist," means an individual who meets the requirements of Rule .05(25)(b) and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

(jj) "Radiation therapy technology," means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

(kk) "Radioactive drug," means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

(ll) "Sealed source," means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(mm) "Sealed Source and Device Registry," means the national registry that contains the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(nn) "Stereotactic radiosurgery," means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a treatment site.

(oo) "Structured educational program," means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(pp) "Teletherapy," as used in this Rule, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(qq) "Temporary jobsite," as used in this Rule, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

(rr) "Therapeutic dosage," means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(ss) "Therapeutic dose," means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(tt) "Treatment site," means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(uu) "Type of use," means use of radioactive material as specified under Rule .05(41), (44), (48), (55), (65), (67) or (85).

(vv) "Unit dosage," means a dosage that:

1. Is obtained or prepared in accordance with the regulations for uses described in Rule .05(41), (44), (48); and
2. Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(ww) "Written directive," means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Rule .05(19).

(xx) "Associate Radiation Safety Officer," means an individual who:

1. Meets the requirements in 391-3-17-.05(22) and .05(27); and
2. Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

(yy) "Ophthalmic physicist," means an individual who:

1. Meets the requirements in 391-3-17-.05(27) and 391-3-17-.05(64)(c)2.; and

2. Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the Commission or an Agreement State;

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

(3) **Maintenance of Records.** Each record required by Rule .05 must be legible throughout the retention period specified by each Division Rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(4) **Provisions for Research Involving Human Subjects.** A licensee may conduct research involving human subjects using radioactive material provided:

(a) That the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Division license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(b) The research involving human subjects authorized in .05(4)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in Rule .05(4) relieves licensees from complying with the other requirements in Rule .05.

(5) **U.S. Food and Drug Administration, Federal, and State Requirements.** Nothing in Rule .05 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

(6) **Implementation.**

(a) A licensee shall implement the provisions in Rule .05 on July 1, 2003.

(b) When a requirement in Rule .05 differs from the requirement in an existing license condition, the requirement in Rule .05 shall govern.

(c) Any existing license condition that is not affected by a requirement in Rule .05 remains in effect until there is a license amendment or license renewal.

(d) If a license condition exempted a licensee from a provision of Rule .05 on July 1, 2003, it will continue to exempt a licensee from the corresponding provision in Rule .05.

(e) If a license condition cites provisions in Rule .05 that will be deleted on July 1, 2003, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(f) Licensees shall continue to comply with any license condition that requires it to implement procedures required by Rule .05(70), (76), (77) and (78) until there is a license amendment or renewal that modifies the license condition.

**(7) License Required.**

(a) A person may manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Director, the Nuclear Regulatory Commission or an Agreement State, or as allowed in Rule .05(7)(b) or (7)(c).

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Rule .05 under the supervision of an authorized user as provided in Rule .05(18), unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in Rule .05 under the supervision of an authorized nuclear pharmacist or authorized user as provided in Rule .05(18), unless prohibited by license condition.

**(8) Application for License, Amendment, or Renewal.**

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of radioactive material as described in Rule .05(41), (44), (48), (55), (65), (67) or (85) must be made by:

1. Filing an original Application for Radioactive Materials License, and
2. Submitting procedures required by sections Rule .05(70), (76), (77), and (78), as applicable.

(c) A request for a license amendment or renewal must be made by:

1. Submitting an original in letter format.
2. Submitting procedures required by sections Rule .05(70), (76), (77) and (78), as applicable.

(d) In addition to the requirements in (8)(b) and (8)(c), an application for a license or amendment for medical use of radioactive material as described in (85) of Rule .05 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Rule .05(1) through Rule .05(40), as well as any specific information on:

1. Radiation safety precautions and instructions;
2. Training and experience of proposed users;
3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(e) The applicant or licensee shall also provide any other information requested by the Division in its review of the application.

(f) An applicant that satisfies the requirements specified in Rule [.02\(10\)\(b\)](#) may apply for a Type A specific license of broad scope.

**(9) Mobile Medical Service Administrative Requirements.**

(a) The Director shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the clinic's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

(c) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(d) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with Rule .05(97).

(f) A mobile medical service licensee shall maintain on each mobile unit:

1. The current operating and emergency procedures;
2. A copy of the license;
3. Copies of the letter required by .05(9)(b);
4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

(g) A mobile medical service licensee shall maintain records required by Rules [.03](#) and .05 of this Chapter at a location within the Division's jurisdiction that is:

1. A single address of use:

(i) Identified as the records retention location; and

(ii) Staffed at all reasonable hours by individual(s) authorized to provide the Division with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Division.

(10) **License Amendments.** A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses radioactive material for a type of use that is permitted under Rule .05, but that is not authorized on the licensee's current license issued pursuant to Rule .05;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

1. For an authorized user, an individual who meets the requirements in Rule .05(27) and (43)(a), Rule .05(47)(a), (52)(a), (53)(a), (54)(a), (63)(a), (64)(a), (66)(a), or (84)(a) or;
2. For an authorized nuclear pharmacist, an individual who meets the requirements in Rule .05(24)(a) and (27);
3. For an authorized medical physicist, an individual who meets the requirements in Rule .05(23)(a) and (27);
4. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or Licensing State license or other equivalent permit or license recognized by the Division that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or
5. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Nuclear Regulatory Commission or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers, except as provided in (15)(c);

(d) Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except as specified in (11)(b)4.;

(f) Before it changes the address(es) of use identified in the application or on the license;

(g) Before it changes statements, representations, and procedures which are incorporated into the license; and

(h) Before it releases licensed facilities for unrestricted use.

**(11) Notifications.**

(a) A licensee shall provide to the Division a copy of the board certification, the Nuclear Regulatory Commission, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist, pursuant to (10)(b).

(b) A licensee shall notify the Division by letter no later than 30 days after:

1. A Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
2. The licensee's mailing address changes;
3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Rule [.02\(13\)\(b\)](#) of these regulations; or
4. The licensee has added to or changed the areas where radioactive material is used in accordance with Rule .05(41) and (44).

**(12) Exemptions Regarding Type A Specific Licenses of Broad Scope.** A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(a) The provisions of (8)(d) of these regulations, regarding the need to file an amendment to the license for medical uses of radioactive material, as described in .05(85);

(b) The provisions of (10)(b) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;

(c) The provisions of (10)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;

(d) The provisions of .05(11)(a) regarding notification to the Division for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and

(e) The provisions of .05(21)(a) regarding suppliers for sealed sources.

**(13) License Issuance.**

(a) The Director shall issue a license for the medical use of radioactive material if:

1. The applicant has filed Application for Radioactive Materials License in accordance with the instructions in .05(8);

2. The applicant has paid any applicable fee;

3. The applicant meets the requirements of Rule [.02](#) of this Chapter; and

4. The Director finds the applicant equipped and committed to observe the safety standards established by the Division in these Rules for the protection of the public health and safety.

(b) The Director shall issue a license for mobile services if the applicant:

1. Meets the requirements in .05(13)(a); and

2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with .05(37).

**(14) Specific Exemptions.** The Director may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Rule .05 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

**General Administrative Requirements**

**(15) Authority and Responsibilities for the Radiation Protection Program.**

(a) In addition to the radiation protection program requirements of Rule [.03\(4\)](#), a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Division;

2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist, and

3. Radiation protection program changes that do not require a license amendment and are permitted under .05(16);

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that

radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in .05(15)(e), provided the licensee takes the actions required in .05(15)(b), (d), (e) and (h). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and,
4. Verify implementation of corrective actions.

(f) Licensees that are authorized for two or more different types of radioactive material use under Rule .05(48), (55), (67), and (85), or two or more types of units under Rule .05(67) shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(g) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each required meeting in accordance with Rule .05(86)(c).

(h) A licensee shall retain a record of actions taken pursuant to Rule .05(15)(a), (15)(b) and (15)(d) in accordance with Rule .05(86)(a) and (b).

**(16) Radiation Protection Program Changes.**

(a) A licensee may revise its radiation protection program without Division approval if:

1. The revision does not require an amendment under Rule .05(10);
2. The revision is in compliance with the regulations and the license;
3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
4. The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with Rule .05(87).

**(17) Duties of Authorized User and Authorized Medical Physicist.**

(a) A licensee shall assure that only authorized users for the type of radioactive material use:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;
2. Direct, as specified in Rule .05(18) and (19), or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and
3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with Rule .05(7)(b) and (7)(c) and (18).

(b) A licensee shall assure that only authorized medical physicists perform, as applicable:

1. Full calibration measurements as described in Rule .05(73), (74), and (75);
2. Periodic spot checks as described in Rule .05(76), (77), and (78); and
3. Radiation surveys as described in Rule 5(80).

**(18) Supervision.**

(a) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by Rule .05(7)(b) shall:

1. In addition to the requirements in Rule [.07\(3\)](#) of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Rule .05(7)(c), shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Rule .05, and license conditions.

(c) Unless physical presence is required in other sections of Rule .05, a licensee who permits supervised activities under Rule .05(18)(a) and (18)(b) shall require an authorized user to be immediately available to communicate with the supervised individual, and when a written directive is required, be able to be physically present within one hour of notification; and

(d) A licensee that permits supervised activities under Rule .05(18)(a) and (18)(b) is responsible for the acts and omissions of the supervised individual.

**(19) Written Directives.**

(a) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30  $\mu$ Ci), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

2. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

3. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(b) The written directive must contain the patient or human research subject's name and the following:

1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

4. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

5. For all other brachytherapy including LDR, MDR, and PDR:

(i) Prior to implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose); or

6. For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date.

(c) The licensee shall retain the written directive in accordance with Rule .05(88).

**(20) Procedures for Administrations Requiring a Written Directive.**

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient's or human research subject's identity is verified before each administration; and

2. Each administration is in accordance with the written directive.

(b) The procedures required by Rule .05(20)(a) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;
2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
3. Checking both manual and computer-generated dose calculations;
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Rule .05(67);
5. Determining if a medical event, as defined in Rule .05(115), has occurred; and
6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(c) A licensee shall retain a copy of the procedures required under subparagraph (a) in accordance with 391-3-17-.05(20) and (88).

**(21) Suppliers for Sealed Sources or Devices for Medical Use.** For medical use, a licensee may only use:

(a) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Rule .02 of this Chapter or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; or

(b) Sealed sources or devices non-commercially transferred from Rule .05 licensee or a Nuclear Regulatory Commission, an Agreement State or a Licensing State medical use licensee.

**(22) Training for Radiation Safety Officer.** Except as provided in Rule .05(26), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in Rule .05(15) to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rule .05(22)(d) and (e), and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. (i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. (i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(I) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(47) or .05(52); and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b) 1. Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Radiation biology; and

(V) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Nuclear Regulatory Commission, Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission, Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive byproduct material. The full-time radiation safety experience must involve the following;

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(III) Securing and controlling radioactive material;

(IV) Using administrative controls to avoid mistakes in the administration of radioactive material;

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(VI) Using emergency procedures to control radioactive material; and

(VII) Disposing of radioactive material; or

2. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in subparagraphs (b)1. and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c) 1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under Rule .05(23)(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or Associate Radiation Safety Officer and who meets the requirements in .05(22)(d); or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or an Agreement State license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in subparagraph .05(22)(d); or

3. Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in subparagraph .05(22)(d).

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

**(23) Training for Authorized Medical Physicist.** Except as provided in Rule .05(26) the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in .05(23)(c) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have 2 years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(63) or .05(84); and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b) 1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

- (i) Performing sealed source leak tests and inventories;
- (ii) Performing decay corrections;
- (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in .05(23)(c) or .05(23)(b)1. and .05(23)(c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in Rule .05(23) and .05(26), or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

**(24) Training for an Authorized Nuclear Pharmacist.** Except as provided in Rule .05(26), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

- 1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
- 2. Hold a current, active license to practice pharmacy;
- 3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and
- 4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b) 1. Has completed 700 hours in a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving:

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;

(III) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(IV) Using administrative controls to avoid misadministrations in the administration of radioactive material; and

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in Rule .05(24)(b)1. and has achieved a level of competency sufficient to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist and operate a nuclear pharmacy, and

(c) Licensed as a Nuclear Pharmacist by the Georgia Board of Pharmacy.

**(25) Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.**

(a) The licensee shall require a nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in:

(i) Nuclear Medicine by the Nuclear Medicine Technology Certification Board;

(ii) Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,

2. Is board eligible to take the CNMT or ARRT(N) examinations; or,

3. Has successfully completed a training program in nuclear medicine which has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,

4. Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or,

5. Has completed 80 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) Administering dosages to patients or human research subjects; and

(iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a nuclear medicine technologist.

(b) The licensee shall require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or

2. Is board eligible to take the ARRT(T) examination; or,

3. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology<sup>1</sup>; or,

4. Has performed as a full-time radiation therapist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or

5. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Assisting the authorized user in simulating the patient for treatment;

(III) Preparing the patient for treatment;

- (IV) Implementing treatment plans as prescribed by the authorized user;
  - (V) Providing written documentation of treatment setup and patient treatments;
  - (VI) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
  - (VII) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
  - (VIII) Delivering doses to patients or human research subjects under the supervision of the authorized user;
  - (IX) Preparing, implanting, and removing sealed sources;
  - (X) Delivering dose to patients or human research subjects;
  - (XI) Maintaining running inventories of material on hand;
  - (XII) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,
  - (XIII) Properly implementing emergency procedures and
    - (iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a radiation therapist.
- (c) Individuals working as nuclear medicine technologists or radiation therapists prior to July 1, 2003 for a facility holding a Division license need not comply with the training requirements of this section.
- (d) The licensee shall maintain records of the above training as specified in Rule .05(100).

**(26) Provisions for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.**

- (a) 1. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Division, Nuclear Regulatory Commission or Agreement State license or on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of this rule, need not comply with the training requirements of Rules .05(22), .05(23), or .05(24), respectively except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in Rule .05(22) or .05(23), as appropriate, for any material or uses for which they were not authorized prior to this date.
2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Rule .05(22) to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.
3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Rule .05(23), for those materials and uses that these individuals performed on or before October 24, 2005.

4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(22), .05(23) or .05(24), respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b) 1. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Director, Nuclear Regulatory Commission or Agreement State, a permit issued by a Director, Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before the effective date of this rule who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Director, Nuclear Regulatory Commission or Agreement State, a permit issued by a Director, Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized on or before October 24, 2005, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84), as follows:

(i) For uses authorized under Rules .05(41) or .05(44), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under Rule .05(48), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under Rules .05(55) or .05(67), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under Rules .05(65), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84) respectively, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for

medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on the Division licenses for the same uses for which these individuals are authorized.

(27) **Recentness of Training.** The training and experience specified in Rule .05 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

## **GENERAL TECHNICAL REQUIREMENTS**

(28) **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures that have been approved by the Division. The licensee shall conduct quality control procedures in accordance with written procedures.

### **(29) Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.**

(a) For direct measurements performed in accordance with Rule .05(31), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(b) A licensee shall test the instrumentation required in Rule .05(29)(a) in accordance with nationally recognized standards or the manufacturer's instructions.

(c) The tests required in Rule .05(29)(b) shall include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

(d) A licensee shall retain a record of each instrument test required by Rule .05(29) in accordance with Rule .05(91).

### **(30) Calibration of Survey Instruments.**

(a) A licensee shall ensure that the survey instruments used to show compliance with Rule .05 and Rule .03 of this Chapter, have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of Rule .05(30)(a), the licensee shall:

1. Calibrate all required scale readings up to 10 millisievert (1,000 mrem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisievert (2 and 1,000 mrem) per hour; and

(iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

3. Conspicuously note on the instrument the date of calibration.

(c) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

(d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each survey instrument calibration in accordance with Rule .05(92).

**(31) Determination of Dosages of Radioactive Material for Medical Use.**

(a) A licensee shall determine and record the activity of each dosage prior to medical use.

(b) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.

(c) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.

(d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by Rule .05(31)(a) through (31)(c) in accordance with Rule .05(93).

**(32) Authorization for Calibration, Transmission and Reference Sources.** Any person authorized by Rule .05(7) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerel (30 mCi) each;

(b) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerel (15 mCi);

(c) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

1. 7.4 megabecquerel (200  $\mu$ Ci); or

2. 1,000 times the quantities in Schedule B of Rule .02(21)(b) of this Chapter; and

(d) Technetium-99m in amounts as needed.

**(33) Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Division.

(b) A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Rule .03 of this Chapter.

2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Division, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) If the leak test reveals the presence of 185 becquerel (0.005  $\mu\text{Ci}$ ) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Rules [.02](#) and [.03](#) of this Chapter; and

2. File a report with the Division within 5 days of receiving the leak test results in accordance with Rule [.05\(117\)](#).

(d) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with Rule [.05\(94\)](#).

(34) **Labels.** Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(35) **Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

**(36) Surveys for Ambient Radiation Dose Rate and Contamination.**

(a) Except as provided in Rule [.05\(36\)\(h\)](#), a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by Rule [.05\(36\)\(a\)](#) and (b) so as to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by Rule [.05\(36\)\(a\)](#) and (b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by Rule [.05\(36\)\(e\)](#) so as to be able to detect contamination on each wipe sample of 33.3 becquerel (2,000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by Rule [.05\(36\)\(e\)](#) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by Rule [.05\(36\)\(a\)](#) in area(s) where patients or human research subjects are confined when they cannot be released pursuant to Rule [.05\(37\)](#).

(i) A licensee shall retain a record of each survey in accordance with Rule [.05\(95\)](#)

**(37) Release of Individuals Containing Radioactive Drugs or Implants.**

(a) A licensee may authorize the release of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

(b) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and
2. Information on the potential consequences, if any, of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with Rule .05(96).

(d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with Rule .05(96).

(e) Notwithstanding Rule .05(37)(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(f) The licensee shall immediately notify the Division in accordance with Rule .05(118) if a patient departs prior to an authorized release.

(g) The licensee shall notify the Division in accordance with Rule .05(119):

1. When they are aware that a patient containing radioactive material and who has been released in accordance with Rule .05(37) dies; and,
2. If it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

**(38) Mobile Medical Service Technical Requirements.** A licensee providing mobile medical service shall:

(a) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

(b) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

(d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

(e) Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Rule [.03](#) of this Chapter;

(g) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Division for compliance with airborne release standards; and,

(h) Retain a record of each survey required by Rule .05(38)(f) in accordance with Rule .05(97)(b).

**(39) Storage and Control of Volatiles and Gases.**

(a) A licensee shall store volatile radioactive materials and radioactive gases in the shippers' radiation shield and container.

(b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.

(c) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Rule [.03](#) of this Chapter.

(d) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(e) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

**(40) Decay-in-Storage.**

(a) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and

3. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(b) For radioactive material disposed in accordance with (40)(a) of this section, the licensee shall retain a record of each disposal in accordance with Rule .05(98).

**SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL WRITTEN DIRECTIVE NOT REQUIRED**

**(41) Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required.** A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule [.02](#) of this Chapter or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or

(c) Obtained from and prepared by a Division, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

(42) **Possession of Survey Instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with Rule .05(30).

(43) **Training for Uptake, Dilution, and Excretion Studies.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a unsealed radioactive material for the uses authorized under Rule .05(41) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in Rule .05(43)(c)1.(i) through .05(43)(c)1.(ii)(VI); and

2. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under Rule .05(47) or .05(52) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), (43), (47) or (52) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) Administering dosages to patients or human research subjects; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(43)(c)1. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule .05(41). The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(43)(c)1.

**(44) Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.** A licensee may use, for imaging and localization studies, any radioactive material (except aerosol or gaseous forms) prepared for medical use, in quantities that do not require a written directive as described in Rule .05(19) that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or

(c) Obtained from and prepared by the Division, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA, or

(e) Provided the conditions of Rule .05(39) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Division.

**(45) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

(a) A licensee shall not administer to humans a radioactive drug containing:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15  $\mu$ Ci of Mo-99 per mCi of Tc-99m); or

2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02  $\mu$ Ci of Sr-82 per mCi of Rb-82 chloride); or

3. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2  $\mu$ Ci of Sr-85 per mCi of Rb-82);

(b) To demonstrate compliance with Rule .05(45)(a), the licensee preparing radioactive drugs from radionuclide generators shall:

1. Measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subparagraph .05(45)(a);

2. Before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with subparagraph .05(45)(a).

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with Rule .05(99).

(d) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in Rule .05(45)(a).

(46) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(47) **Training for Imaging and Localization Studies.** Except as provided in Rule .05(26), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Rule .05(44) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in (c)1.(i) through (c)1.(ii)(VII) of this rule; and

2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is listed as an authorized user under Rule .05(52) and meets the requirements in .05(47)(c)1.(ii)(VII) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes, at a minimum:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use;

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Rule .05(26), .05(47) or .05(47)(c)1.(ii)(VII) and Rule .05(52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. An authorized nuclear pharmacist who meets the requirements in 391-3-17-.05(24) or 391-3-17-.05(26) may provide the supervised work experience for subparagraph .05(47)(c)1.(ii)(VII). Work experience must involve:

- (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
  - (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
  - (V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
  - (VI) Administering dosages to patients or human research subjects; and
  - (VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(47)(c)1. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rules .05(41) and .05(44).

The signed attestation must be obtained from either:

- (i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or
- (ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(47)(c)1.

#### **SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL WRITTEN DIRECTIVE REQUIRED**

(48) **Use of Unsealed Radioactive Material for Which a Written Directive is Required.** A licensee may use any unsealed radioactive material identified in subparagraph (52)(b)1.(ii)(VII) prepared for diagnostic or therapeutic medical use for which a written directive is required that has been:

- (a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- (b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or (52), or an individual under the supervision of either as specified in Rule .05(26); or

(c) Obtained from and prepared by the Division, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

(49) **Safety Instruction.** In addition to the requirements of Rule [.07\(3\)](#) of this Chapter:

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with Rule [.05\(37\)](#). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;

2. Visitor control to include the following:

(i) Routine visitation to hospitalized individuals in accordance with Rule [.03](#) of this Chapter;

(ii) Contamination control;

(iii) Waste control; and

(iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule [.05\(101\)](#).

(50) **Safety Precautions.**

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with Rule [.05\(37\)](#), a licensee shall:

1. Quarter the patient or the human research subject either in:

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who cannot be released in accordance with Rule [.05\(37\)](#); and,

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

3. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) The Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule [.05\(119\)](#) if it is possible that any individual could receive exposures in excess of the limits in Rule [.03\(5\)\(i\)](#) of this Chapter as a result of the deceased's body.

(51) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(52) **Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user of radioactive material for the uses authorized under Rule .05(48) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State, and who meets the requirements of Rule .05(52)(b)1(ii)(VII). (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in Rule .05(52)(b)1.(i) through .05(52)(b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(b) 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive that includes:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(52) or equivalent Agreement State, or Nuclear Regulatory Commission requirements. The work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

(VI) Reserved.

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by Rule .05(52)(b)1.(ii):

(i) Oral administration of less than or equal to 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131, for which a written directive is required;

(ii) Oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131<sup>2</sup>;

(iii) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV, for which a written directive is required; and/or

(iv) Parenteral administration of any other radionuclide, for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(52)(b)1., and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule .05(48).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(52)(b)1.

**(53) Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerel (33 millicurie) for which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerel (33 millicurie), for which a written directive is required, to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in .05(53)(c)1. and .05(53)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under Rule (52) for uses listed in (52)(b)1.(ii)(VII)(i) or (ii), or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and
- (v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), (53) or (54), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b) must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(i) or (ii); the work experience must involve:

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;
- (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(53)(c)1. and (53)(c)2. and is able to independently fulfill the radiation safety-related duties as an authorized user for medical uses authorized under .05(48).

The signed attestation must be obtained from either:

- (i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or
- (ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(53)(c)1. and 2.

**(54) Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerel (33 millicurie) for which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerel (33 millicurie), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in Rules .05(54)(c)1. and .05(54)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under Rule .05(52) for uses listed in Rule .05(52)(b)1.(ii)(VII)(ii), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), or (54), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii); the work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(54)(c)1. and .05(54)(c)2. and is able to independently fulfill the duties as an authorized user for medical uses authorized under Rule .05(48). The written attestation must be signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(52), or .05(54), or equivalent Agreement State Licensing State or Nuclear Regulatory Commission requirements. The preceptor authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii).

(54.1) Except as provided in Rule .05(26) the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under Rule .05(52) for uses listed in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(b) Is an authorized user under Rules .05(63), .05(84), or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in .05(54.1)(d); or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State under Rules .05(63) or .05(84), and who meets the requirements in paragraph .05(54.1)(d).

(d) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), .05(52), .05(54.1) or equivalent Agreement State or Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Rule .05(52) or .05(54.1) must have experience in administering dosages as specified in .05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in .05(54.1)(d)1. and (d)2. and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive.

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (52), (54.1) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (52) or (54.1), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(54.1)(d)1. and 2.

### **Manual Brachytherapy**

**(55) Use of Sealed Sources for Manual Brachytherapy.** A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

### **(56) Surveys After Source Implant and Removal.**

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

### **(57) Brachytherapy Sources Inventory.**

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with Rule .05(103).

**(58) Safety Instruction.** In addition to the requirements of Rule [.07\(3\)](#) of this Chapter:

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with Rule .05(37). Instruction must be commensurate with the duties of the personnel and shall include the following:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;

4. Visitor control, including both:

- (i) Routine visitation of hospitalized individuals in accordance with Rule [.03\(5\)\(i\)1.\(i\)](#) of this Chapter; and
- (ii) Visitation authorized in accordance with Rule [.03\(5\)\(i\)2.](#) of this Chapter; and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule [.05\(119\)](#) if it is possible for any individual to receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule [.05\(101\)](#).

**(59) Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.**

(a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with Rule [.05\(37\)](#), a licensee shall:

1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

1. Dislodged from the patient; or

2. Lodged within the patient following removal of the source applicators.

(c) Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

**(60) Calibration Measurements of Brachytherapy Sealed Sources.**

(a) Prior to the first medical use of a brachytherapy sealed source on or after July 1, 2003, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of Rule [.05\(72\)\(a\)](#);

2. Determine source positioning accuracy within applicators; and

3. Use published protocols accepted by nationally recognized bodies to meet the requirements of Rule [.05\(60\)\(a\)1.](#) and [.05\(60\)\(a\)2.](#)

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with Rule [.05\(60\)\(a\)](#).

(c) A licensee shall mathematically correct the outputs or activities determined in Rule [.05\(60\)\(a\)](#) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to Rule [.05\(60\)\(a\)](#), [\(60\)\(b\)](#), or [\(60\)\(c\)](#).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with Rule .05(60)(a), (60)(b), and (60)(c).

(f) A licensee shall retain a record of each calibration in accordance with Rule .05(104).

(g) A licensee shall retain a record of decay calculations required by Rule .05(60)(e) in accordance with Rule .05(105).

**(61) Therapy-related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine radioactive source positions from radiographic images.

**(62) Possession of Survey Instruments.** A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

**(63) Training for Use of Manual Brachytherapy Sources.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Rule .05(55) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in .05(26), (63) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution authorized to use byproduct material under Rule .05(55), involving:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of material on hand;

(V) Using administrative controls to prevent a misadministration involving the use of radioactive material; and

(VI) Using emergency procedures to control radioactive material; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(63) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by Rule .05(63)(b).1.(ii); and

3. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(63) or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rules .05(63)(b)1. and (63)(b)2. and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under in Rule .05(55).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

**(64) Training for Ophthalmic Use of Strontium-90.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under Rule .05(55) to be a physician who:

(a) Is an authorized user under Rule .05(63) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or,

(b) 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice, and that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

- (i) Examination of each individual to be treated;
- (ii) Calculation of the dose to be administered;
- (iii) Administration of the dose; and
- (iv) Follow-up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(63) or .05(64) or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rule .05(64)(b)1. and 2., and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

(c) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subparagraph .05(64)(d) are performed by either:

- 1. An authorized medical physicist; or
- 2. An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(I) The creation, modification, and completion of written directives;

(II) Procedures for administrations requiring a written directive; and

(III) Performing the calibration measurements of brachytherapy sources as detailed in Rule (.05)(60).

(d) The individuals who are identified in subparagraph .05(64)(c) must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule (.05)(60); and

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subparagraph .05(64)(c) will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(e) Licensees must retain a record of the activity of each strontium-90 source in accordance with Rule (.05)(105).

### **Sealed Sources For Diagnosis**

#### **(65) Use of Sealed Sources and Medical Devices for Diagnosis.**

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(20)(a) are met.

**(66) Training for Use of Sealed Sources for Diagnosis and Medical Devices for Diagnosis.** Except as provided in Rule .05(26), the licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under Rule .05(65) to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rules .05(66)(c) and .05(66)(d) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user for uses listed in Rule .05(44) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

**Photon-Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**

**(67) Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.**

(a) A licensee must only use sealed sources:

1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or
2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Rule .05(21)(a) are met.

**(68) Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.**

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(b) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

**(69) Installation, Maintenance, Adjustment, and Repair.**

(a) Only a person specifically licensed by the Director, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Director, an Agreement State, Licensing State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Director, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with Rule .05(106).

**(70) Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or when unattended;
2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and
4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by Rule .05(70)(a)4. must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by Rule .05(70)(a)4.; and
2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2. A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(i) The procedures identified in Rule .05(70)(a)4.; and

(ii) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by Rule .05(70)(d), in accordance with Rule .05(101).

(g) A licensee shall retain a copy of the procedures required by subparagraphs .05(70)(a)4. and (d)2.(ii).

**(71) Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

- (a) A licensee shall control access to the treatment room by a door at each entrance.
- (b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:
  - 1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
  - 2. Cause the source(s) to be shielded promptly when an entrance door is opened; and
  - 3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
- (c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- (d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- (e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
- (f) In addition to the requirements specified in Rule .05(71)(a) through (71)(e), a licensee shall:
  - 1. For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:
    - (i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
    - (ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
  - 2. For high dose-rate remote afterloader unit, require:
    - (i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
    - (ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
  - 3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
  - 4. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.
- (g) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:
  - 1. Remains in the unshielded position; or

2. Lodges within the patient following completion of the treatment.

**(72) Dosimetry Equipment.**

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
2. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been inter-compared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the inter-comparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with Rule .05(72)(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in Rule .05(72)(a).

(c) The licensee shall retain a record of each calibration, inter-comparison, and comparison in accordance with Rule .05(107).

**(73) Full Calibration Measurements on Teletherapy Units.**

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:
  - (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
  - (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
  - (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding 1 year.

(b) To satisfy the requirement of Rule .05(73)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(73)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(73)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(73)(b)1. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by Rule .05(73)(a) and physical decay corrections required by Rule .05(73)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

**(74) Full Calibration Measurements on Remote Afterloader Units.**

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of Rule .05(74)(a), full calibration measurements must include, as applicable, determination of:

1. The output within +/- 5 percent;

2. Source positioning accuracy to within +/- 1 millimeter;

3. Source retraction with backup battery upon power failure; and

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Rule .05(74)(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output.

(e) A licensee shall make full calibration measurements required by Rule .05(74)(a) in accordance with published protocols accepted by nationally recognized bodies.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Rule .05(74)(a) through (74)(e).

(g) A licensee shall mathematically correct the outputs determined in Rule .05(74)(b)1. of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by Rule .05(74)(a) and physical decay corrections required by Rule .05(74)(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

**(75) Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.**

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of Rule .05(75)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent;

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(75)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(75)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(75)(b)1. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by Rule .05(75)(a) and physical decay corrections required by Rule .05(75)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

**(76) Periodic Spot-Checks for Teletherapy Units.**

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b); and
6. The difference between the measurement made in Rule .05(76)(a)5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by Rule .05(76)(a) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in Rule .05(76)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by Rule .05(76)(a) and (76)(d), in accordance with Rule .05(109).

**(77) Periodic Spot-Checks for Remote Afterloader Units.**

(a) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

1. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and
3. After each source installation.

(b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in Rule .05(77)(a). The authorized medical physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(d) To satisfy the requirements of Rule .05(77)(a), spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;

7. Clock (date and time) in the unit's computer; and

8. Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in Rule .05(77)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by Rule .05(77)(d) in accordance with Rule .05(110).

**(78) Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;

2. At the beginning of each day of use; and

3. After each source installation.

(b) The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in Rule .05(78)(a); and

2. Review the results of each spot-check required by Rule .05(78)(a)1. within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of Rule .05(78)(a)1., spot-checks must, at a minimum:

1. Assure proper operation of:

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

2. Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b);

(ii) The difference between the measurement made in Rule .05(78)(c)2.(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of Rule .05(78)(a)2. and (78)(a)3., spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identified in Rule .05(78)(c) that is not operating properly.

(f) If the results of the checks required in Rule .05(78)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by Rule .05(78)(c) and (78)(d) in accordance with Rule .05(111).

**(79) Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
2. Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by Rule .05(77), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
5. Radiation monitors used to indicate room exposures;
6. Source positioning (accuracy); and
7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in Rule .05(79)(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in Rule .05(79)(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by Rule .05(79)(b) in accordance with Rule .05(112).

**(80) Radiation Surveys.**

(a) In addition to the survey requirements in Rule [.03\(8\)](#) of this Chapter, a person licensed pursuant to Rule .05 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by Rule .05(80)(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by Rule .05(80)(a) of this section in accordance with Rule .05(113).

**(81) Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism and other safety components.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Director, an Agreement State, a Licensing State or the Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with Rule .05(114).

**(82) Therapy-Related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

**(83) Possession of Survey Instruments.** A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

**(84) Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a sealed source for a use authorized under Rule .05(67) to be a physician who:

(a) Is certified by a medical specialty board whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in .05(84)(c). (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution that is authorized to use radioactive materials in Rule .05(67), involving:

(I) Reviewing full calibration measurements and periodic spot checks;

(II) Preparing treatment plans and calculating treatment doses and times;

(III) Using administrative controls to prevent a mis-administration involving the use of radioactive material;

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by Rule .05(84)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(84)(b)1. and .05(84)(b)2., and .05(84)(c), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status; and

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (84), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (84), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

#### **Other Medical Uses of Radioactive Material or Radiation from Radioactive Material**

**(85) Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.** A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Rule .05 if:

(a) The applicant or licensee has submitted the information required by Rule .05(8)(b), (8)(c) and (8)(d); and

(b) The applicant or licensee has received written approval from the NRC, an Agreement State, or Licensing State in a license and uses the material in accordance with the regulations and specific conditions the NRC, Agreement State, or Licensing State considers necessary for the medical use of the material.

#### **Records**

**(86) Records of Authority and Responsibilities for Radiation Protection Programs.**

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with Rule .05(15)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by Rule .05(15)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by Rule .05(15)(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) The minutes of each Radiation Safety Committee meeting held in accordance with Rule .05(15)(g) shall include:

1. The date of the meeting;
2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

(87) **Records of Radiation Protection Program Safety Changes.** A licensee shall retain a record of each radiation protection program change made in accordance with Rule .05(16)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(88) **Records of Written Directives.** A licensee shall retain a copy of each written directive as required by Rule .05(19) for 3 years.

(89) **Records of Misadministrations.** A licensee shall retain a record of misadministrations reported in accordance with Rule .05(115) for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(90) **Record of a Dose to an Embryo/Fetus or a Nursing Child.** A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with Rule .05(116) for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(91) **Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.** A licensee shall maintain a record of instrument calibrations required by Rule .05(29) for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(92) **Records of Survey Instrument Calibrations.** A licensee shall maintain a record of instrument calibrations required by Rule .05(30) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(93) **Records of Dosages of Unsealed Radioactive Material for Medical Use.** A licensee shall maintain a record of dosage determinations required by Rule .05(31) for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.11 MBq (30  $\mu$ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(94) **Records of Possession of Sealed Sources and Brachytherapy Sources.** A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Rule .05(33)(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(95) **Records of Surveys for Ambient Radiation Exposure Rate.** A licensee shall retain a record of each survey required by Rule .05(36) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(96) **Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.**

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release,

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by Rule .05(37)(b) were provided to a breast-feeding woman.

**(97) Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.**

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by Rule .05(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by Rule .05(38)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

**(98) Records of Decay-in-Storage.** A licensee shall maintain records of the disposal of licensed materials, as required by Rule .05(40), for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

**(99) Records of Radionuclide Purity.** A licensee shall maintain a record of the radionuclide contaminant concentration tests required by Rule .05(45) for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcurie/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

**(100) Records of Training.** A licensee shall maintain records of training required by Rule .05(25) for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

**(101) Records of Safety Instruction and Training.** A licensee shall maintain a record of safety instructions and training required by Rules .05(49), (58) and (70) for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

**(102) Records of Radiation Surveys of Patients and Human Research Subjects.** A licensee shall maintain a record of the surveys required by Rule .05(56) and (68) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

**(103) Records of Brachytherapy Source Inventory.**

(a) A licensee shall maintain a record of brachytherapy source accountability required by Rule .05(57) for 3 years.

(b) For temporary implants, the record must include:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use;
2. The number and activity of unused sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of temporarily implanted sources removed from the patient or human research subject, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of sources permanently implanted in the patient or human research subject.

(104) **Records of Calibration Measurements on Brachytherapy Sources.** A licensee shall maintain a record of the calibrations on brachytherapy sources required by Rule .05(60) for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(105) **Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.** The licensee shall maintain a record of the activity of a strontium 90 source required by Rule .05(60) for the life of the source. The record must include the date and initial activity of the source as determined under Rule .05(60), and for each decay calculation, the date, and the source activity and the signature of the authorized medical physicist.

(106) **Records of Installation, Maintenance, Adjustment, and Repair.** A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by Rule .05(69) for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(107) **Records of Dosimetry Equipment.**

(a) A licensee shall retain a record of the calibration, inter-comparison, and comparisons of its dosimetry equipment done in accordance with Rule .05(72) for the duration of the license.

(b) For each calibration, inter-comparison, or comparison, the record must include:

1. The date;
2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by Rule .05(72)(a) and (72)(b);
3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and
4. The names of the individuals who performed the calibration, inter-comparison, or comparison.

(108) **Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.**

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by Rule .05(73), (74) and (75) for 3 years.

(b) The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
3. The results and assessments of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units; and
5. The signature of the authorized medical physicist who performed the full calibration.

**(109) Records of Periodic Spot-Checks for Teletherapy Units.**

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Rule .05(76) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

**(110) Records of Periodic Spot-Checks for Remote Afterloader Units.**

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by Rule .05(77) for 3 years.

(b) The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

**(111) Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Rule .05(78) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

**(112) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by Rule .05(79) for 3 years.

(b) The record must include:

1. The date of the check;
2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
3. Notations accounting for all sources before the licensee departs from a facility;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
5. The signature of the individual who performed the check.

**(113) Records of Surveys of Therapeutic Treatment Units.**

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Rule .05(80) for the duration of use of the unit.

(b) The record must include:

1. The date of the measurements;
2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test.

**(114) Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.**

(a) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Rule .05(81) for the duration of use of the unit.

(b) The record must contain:

1. The inspector's radioactive materials license number;

2. The date of inspection;

3. The manufacturer's name and model number and serial number of both the treatment unit and source;

4. A list of components inspected and serviced, and the type of service; and

5. The signature of the inspector.

**Reports**

**(115) Reports and Notifications of Misadministrations.**

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug or the wrong radionuclide for brachytherapy procedures;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(i) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(I) The wrong radionuclide;

(II) The wrong individual or human research subject;

(III) Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or

(IV) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify the Division by telephone no later than the next calendar day after discovery of the misadministration.

(d) The licensee shall submit a written report to the Division within 15 days after discovery of the misadministration.

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

(g) A licensee shall retain a record of a misadministration in accordance with Rule .05(89). A copy of the record required under Rule .05(89) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

**(116) Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.**

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

1. Is greater than 5 mSv (500 mrem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the Division no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

(d) The licensee shall submit a written report to the Division within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

1. The written report must include:

- (i) The licensee's name;
- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect on the embryo/fetus or the nursing child;
- (vi) What actions, if any, have been taken, or are planned, to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under Rule .05(116)(a) or (116)(b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with Rule .05(90). A copy of the record required under Rule .05(90) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(117) **Reports of Leaking Sources.** A licensee shall file a report with the Division within 5 days if a leakage test required by Rule .05(33) reveals the presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(118) **Reports of Patient Departure Prior to Authorized Release.**

(a) A licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under Rule .05(37)(a).

(b) The licensee shall submit a written report to the Division within 30 days after discovery of the unauthorized departure. The written report must include:

1. The licensee's name;
2. The date and time of the unauthorized departure;
3. The projected date and time when release would have occurred;
4. The address of the patient's or human research subject's home or anticipated destination following departure;
5. The radionuclide, chemical and physical form and calculated activity at time of release;
6. The apparent reason(s) for the departure prior to authorized release; and
7. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(119) **Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.**

(a) The licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of limits specified in Rule [.03\(5\)\(i\)](#) of this Chapter as a result of the deceased's body.

(b) The licensee shall submit a written report to the Division within 30 days after discovery that the patient or human research subject referenced in (119)(a) has died. The written report must include:

1. The licensee's name;
2. The date of death;
3. The radionuclide, chemical and physical form and calculated activity at time of death; and,
4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisievert (500 mrem).

**(120) Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.**

(a) The licensee shall notify by telephone the Georgia Department of Natural Resources, Environmental Protection Division and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 391-3-17-.05(45)(a) at the time of generator elution. The telephone report to the Georgia EPD must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(b) By an appropriate method listed in [391-3-17-.01\(13\)](#), the licensee shall submit a written report to Georgia Department of Natural Resources, Environmental Protection Division within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subparagraph .05(120)(a).

<sup>1</sup> "Essentials and guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

<sup>2</sup> Experience with at least 3 cases in category (VII)(ii) also satisfies the requirement in category (VII)(i).

**AUTHORITY:** O.C.G.A. § [31-13-1](#) et seq., as amended.

**HISTORY:** Original Rule entitled "Use of Radionuclides in the Healing Arts" adopted. F. May 2, 1991; eff. May 22, 1991.

**Amended:** F. Feb. 24, 1994; eff. Mar. 16, 1994.

**Amended:** F. Oct. 4, 1994; eff. Oct. 24, 1994.

**Amended:** F. Apr. 16, 1997; eff. May 6, 1997.

**Amended:** F. Mar. 29, 2002; eff. Apr. 18, 2002.

**Repealed:** New Rule of same title adopted. F. May 30, 2003; eff. July 1, 2003, as specified by the Agency.

**Amended:** F. Oct. 17, 2008; eff. Nov. 6, 2008.

**Amended:** F. Jan. 8, 2014; eff. Jan. 28, 2014.

**Amended:** F. Apr. 11, 2016; eff. May 1, 2016.

**Amended:** New title, "Use of Radionuclides in the Healing Arts." F. June 1, 2017; eff. June 21, 2017.

**Amended:** F. Jan. 28, 2019; eff. Feb. 17, 2019.

**Amended:** F. Feb. 26, 2020; eff. Mar. 17, 2020.

## **391-3-17-.07 Notices, Instructions, and Reports To Workers: Inspection and Investigations**

(1) **Purpose and Scope.** This Rule, 391-3-17-.07, establishes requirements for notices, instructions, and reports by licensees to individuals engaged in activities under a license and options available to such individuals in connection with Division inspections of licensees to ascertain compliance with the provisions of the Act and Regulations, Orders, and licenses issued thereunder regarding radiological working conditions. The Regulations in this Rule apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed by the Director pursuant to Rules [391-3-17-.02](#), [.04](#), [.05](#), [.08](#), and [.09](#).

### **(2) Posting of Notices to Workers.**

(a) Each licensee shall post current copies of the following documents:

1. This Rule and Rule [391-3-17-.03](#) of this Chapter;
2. The license, license conditions and documents incorporated into the license by reference and amendments thereto;
3. The operating procedures applicable to activities under the license; and
4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or Order issued pursuant to this Chapter, and any response from the licensee.

(b) If posting of a document specified in (2)(a)1., 2., or 3. of this Rule is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

(c) Division's form "Notice to Employees" shall be posted by each licensee.

(d) Division documents posted pursuant to (2)(a)4. of this Rule shall be posted within 5 working days after receipt of the documents from the Division; the licensee's response, if any, shall be posted within five working days after dispatch from the licensee. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices, or forms posted pursuant to (2) of this Rule shall appear in a sufficient number of places to permit individuals engaged in work under the license to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous and shall be replaced if defaced or altered.

### **(3) Instructions to Workers.**

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be:

1. Kept informed of the storage, transfer, or use of sources of radiation in the licensee's facility;
2. Instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

3. Instructed in, and instructed and required to observe, to the extent within the workers' control, the applicable provisions of this Chapter and the license for the protection of personnel from exposures to radiation or radioactive material;
4. Instructed of their responsibility to report promptly to the licensee any condition which may constitute, lead to, or cause a violation of the Act, this Chapter, and the license or unnecessary exposure to radiation or radioactive material;
5. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
6. Advised as to the radiation exposure reports which workers shall be furnished pursuant to (4) of this Rule.

(b) In determining those individuals subject to the requirements of (3)(a) above, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material which can reasonably be expected to occur during the life of the facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

**(4) Notifications and Reports to Individuals.**

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, when required by Rule [391-3-17-.03\(8\)\(b\)](#) of this Chapter, shall be reported to the individual as specified in (4) of this Rule. The information reported shall include data and results obtained pursuant to this Chapter, Orders, or license conditions, as shown in records maintained by the licensee pursuant to this Chapter. Each notification and report shall:

1. Be in writing;
2. Include appropriate identifying data such as the name of the licensee, the name of the individual, and the individual's identification number, preferably social security number;
3. Include the individual's exposure information; and
4. Contain the following statement: "This report is furnished to you under the provisions of Rule 391-3-17-.07. You should preserve this report for further reference."

(b) Each licensee shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee pursuant to Rule [391-3-17-.03\(14\)\(g\)](#) of this Chapter. The licensee shall provide an annual report to each individual monitored under .03(8)(b) of the dose received in that monitoring year if:

1. The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or
2. The individual requests his or her annual dose report.

(c) Each licensee shall furnish a written report of a worker's exposure to sources of radiation at the request of the worker formerly engaged in activities controlled by the licensee. The report shall include the dose record for each year the worker was required to be monitored pursuant to Rule [391-3-17-.03\(8\)\(b\)](#). Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license in which the worker participated during this period.

(d) When a licensee is required pursuant to Rule [391-3-17-.03\(15\)\(b\), \(c\), and \(d\)](#) of this Chapter to report to the Division any exposure of an individual to radiation or radioactive material, the licensee shall also provide the

individual a report on his or her exposure data included in the report to the Division. Such reports shall be transmitted at a time not later than the transmittal to the Division.

(e) At the request of a worker who is terminating employment with the licensee in work involving exposure to radiation or radioactive material, during the current year, each licensee shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

**(5) Presence of Representatives of Licensees and Workers During Inspection.**

(a) Each licensee shall afford to the Division at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to this Chapter.

(b) During an inspection, Division inspectors may consult privately with workers as specified in (6) of this Rule. The licensee may accompany Division inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Division inspections, the licensee shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee and shall have received instructions as specified in (3) of this Rule.

(e) Different representatives of the licensee and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee and the workers' representative, an individual who is not routinely engaged in work under control of the licensee, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Division inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of (5) of this Rule, Division inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

**(6) Consultation with Workers During Inspections.**

(a) Division inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of this Chapter and the license to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, this Chapter, or license conditions, or any unnecessary exposure of an individual to sources of radiation under the licensee's control. Any such notice in writing shall comply with the requirements of (7)(a) of this Rule.

(c) The provisions of (6)(b) of this Rule shall not be interpreted as authorization to disregard instructions pursuant to (3) of this Rule.

**(7) Requests by Workers for Inspections**

(a) Any worker or representative of workers believing that a violation of the Act, this Chapter, or license conditions exists or has occurred in work under a license with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Division's Radioactive Materials Program. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee by the Division no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Division, except for good cause shown.

(b) If, upon receipt of such notice, the Division determines that the complaint meets the requirements set forth in (7)(a) of this Rule, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to (7) of this Rule need not be limited to matters referred to in the complaint.

(c) No licensee or contractor or subcontractor of a licensee shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this Chapter or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this Rule.

#### **(8) Inspections Not Warranted; Informal Review**

(a) If the Division's Radioactive Materials Program determines, with respect to a complaint under (7) of this Rule, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Radioactive Materials Program shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of (7)(a) of this Rule. The complainant may obtain review of such determination by submitting a written statement of position with the Director of the Environmental Protection Division. The Division will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position to the Director of the Environmental Protection Division who will provide the complainant with a copy of such statement by certified mail.

(b) Upon the request of the complainant, the Director of the Environmental Protection Division may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Director of the Environmental Protection Division shall affirm, modify, or reverse the determination of the Manager of Radioactive Materials Program, and furnish the complainant and the licensee a written notification of the decision and the reason for it.

**AUTHORITY:** O.C.G.A. § [31-13-1](#) et seq., as amended.

**HISTORY:** Original Rule entitled "Notices, Instructions and Reports to Workers Inspections" adopted. F. May 2, 1991; eff. May 22, 1991.

**Amended:** F. Feb. 24, 1994; eff. Mar. 16, 1994.

**Amended:** F. Oct 4, 1994; eff. Oct. 24, 1994.

**Amended:** F. Apr. 16, 1997; eff. May 6, 1997.

**Amended:** F. Mar. 29, 2002; eff. Apr. 18, 2002.

**Amended:** F. Jan. 8, 2014; eff. Jan. 28, 2014.

**Amended:** F. Jan. 28, 2019; eff. Feb. 17, 2019.

**Amended:** New title "Notices, Instructions, and Reports To Workers: Inspection and Investigations." (Rule amended only to change the title, as specified by Agency.) F. Feb. 26, 2020; eff. Mar. 17, 2020.

### **391-3-17-.10 Administration**

(1) Scope. The provisions of this Rule, 391-3-17-.10, shall apply to the administrative procedures required by this Chapter.

(2) Administration.

(a) Administrative Examination of Applications. Applications for the issuance of a license, amendment of a license at the request of the holder, and renewal of a license will be given a docket or other identifying number for administrative examination. The applicant may be required to submit additional information and may be requested to confer in formally regarding the application. The Division will give to others such notice of the filing of applications as is required under the applicable provisions of this Chapter and such additional notices as it deems appropriate.

(b) Effect of Timely Renewal Application. In the case of an application for renewal, if the licensee has made application for the renewal of an existing license at least 30 days prior to its expiration date, the license shall not be deemed to have expired until such application shall have been determined.

(c) Filing of Papers. Unless otherwise specified, papers required to be filed with the Division shall be filed with the Environmental Protection Division, Radioactive Materials Program, 4244 International Parkway, Suite 120 Atlanta, Georgia 30354. Papers required to be filed with the Division shall be deemed filed upon actual receipt with the Division at the location specified. Unless otherwise specified, the filing, when by mail, shall upon actual receipt be deemed complete as of the date of deposit in the mail. Papers may be filed at the Division's offices in Atlanta, Georgia.

(d) Payment of Fees. All licensees shall remit annual fees in accordance with Table 1, the Radioactive Materials License Fee Schedule. Annual fee payments for general and specific licenses are due before the end of the calendar year for the following calendar year. New licensees shall be in voiced for annual fees at a prorated rate. Such fees shall be due and payable thirty (30) days after the invoice date. Fees for applications for specific licenses, and annual fees for reciprocity applicants, shall accompany the request. An application fee must accompany renewal applications that are submitted after a license has expired. Licensees with fees which are delinquent shall not have any request for amendment or renewal of their licenses, except in the interest of public health and safety, honored by the Division until such fees are paid in full or a payment plan has been accepted by the Division.

Table 1  
Radioactive Materials License Fee Schedule

| License Category                               | Fee Category | New License Application Fee | Annual Fee, Nominal | Annual Fee, Small Entity [See subparagraph (e)] | Annual Fee, Lower Tier [See subparagraph (f)] |
|--|--------------|-----------------------------|---------------------|---|---|
| Medical Teletherapy                            | A.1.a        | \$3,256.00                  | \$6,623.00          | \$2,026.50                                      | \$1,212.75                                    |
| Stereotactic Radio surgery (i.e., Gamma Knife) | A.1.b        | \$3,256.00                  | \$6,623.00          | \$2,026.50                                      | \$1,212.75                                    |
| Broad Medical                                  | A.10         | \$3,145.00                  | \$17,057.00         | \$4,550.00                                      | \$3,736.25                                    |
| Eye Applicators                                | A.11         | \$999.00                    | \$3,182.00          | \$1,982.75                                      | \$1,169.00                                    |
| Source Material                                | A.12         | \$1,998.00                  | \$4,588.00          | \$435.75  | \$435.75                                      |
| Depleted Uranium                               | A.12         | \$222.00                    | \$666.00            | \$266.00  | \$266.00                                      |

| License Category   | Fee Category | New License Application Fee | Annual Fee, Nominal | Annual Fee, Small Entity [See subparagraph (e)] | Annual Fee, Lower Tier [See subparagraph (f)] |
|--|--------------|-----------------------------|---------------------|---|---|
| Institutional Medical-Mult. Use (Including HDR)              | A.2.a        | \$999.00                    | \$3,182.00          | \$3,150.00                                      | \$2,336.25                                    |
| Institutional Medical-Mult. Use                              | A.2.b        | \$999.00                    | \$3,182.00          | \$1,982.75                                      | \$1,169.00                                    |
| Institutional Medical-Mult. Use (diagnostic only)            | A.2.c        | \$999.00                    | \$3,182.00          | \$1,750.00                                      | \$936.25                                      |
| Institutional Medical-Single Use (therapy only)              | A.3          | \$999.00                    | \$3,182.00          | \$1,982.75                                      | \$1,169.00                                    |
| Private Practice (Therapy-HDR)                               | A.4.a        | \$999.00                    | \$3,182.00          | \$3,150.00                                      | \$2,336.25                                    |
| Private Practice (Limited Therapy)                           | A.4.b        | \$999.00                    | \$3,182.00          | \$1,982.75                                      | \$1,169.00                                    |
| Private Practice (Diagnostic Only)                           | A.4.c        | \$999.00                    | \$3,182.00          | \$1,837.50                                      | \$1,023.75                                    |
| Private Practice (Veterinary)                                | A.4.d        | \$555.00                    | \$1,813.00          | \$1,750.00                                      | \$936.25                                      |
| In-Vitro Specific Licenses                                   | A.5          | \$555.00                    | \$1,813.00          | \$1,470.00                                      | \$831.25                                      |
| In-Vitro General Licenses                                    | A.6          | \$0.00                      | \$100.00            | \$100.00  | \$100.00                                      |
| Bone Mineral Analyzers                                       | A.7          | \$999.00                    | \$3,182.00          | \$1,750.00                                      | \$936.25                                      |
| Nuclear Pharmacy   | A.8.a.1      | \$2,405.00                  | \$6,253.00          | \$3,990.00                                      | \$3,176.25                                    |
| Medical Manufacturer for Distribution                        | A.8.a.2      | \$2,405.00                  | \$6,253.00          | \$2,357.25                                      | \$1,543.50                                    |
| Medical Distribution or Redistribution Only (sealed sources) | A.8.b.1      | \$1,885.72                  | \$3,717.19          | \$1,692.25                                      | \$878.50                                      |
| Medical Distribution or Redistribution Only (GL)             | A.8.b.2      | \$407.00                    | \$1,184.00          | \$1,184.00                                      | \$691.25                                      |
| Mobile Nuclear Medicine                                      | A.9.a        | \$999.00                    | \$3,182.00          | \$2,275.00                                      | \$1,461.25                                    |
| Mobile HDR   | A.9.b        | \$999.00                    | \$3,182.00          | \$2,275.00                                      | \$1,461.25                                    |
| Special Nuclear Material (sealed sources in devices)         | B.1.a        | \$481.00                    | \$1,332.00          | \$1,036.00                                      | \$572.25                                      |
| Special Nuclear Material (power sources in devices)          | B.1.b        | \$925.00                    | \$2,701.00          | \$990.50  | \$526.75                                      |
| Special Nuclear Material (other)                             | B.2          | \$925.00                    | \$2,701.00          | \$1,895.25                                      | \$1,081.50                                    |

| License Category                                     | Fee Category | New License Application Fee | Annual Fee, Nominal | Annual Fee, Small Entity [See subparagraph (e)] | Annual Fee, Lower Tier [See subparagraph (f)] |
|--|--------------|-----------------------------|---------------------|---|---|
| Pacemaker, By product or SNM -- Medical Inst         | B.3          | \$999.00                    | \$3,182.00          | \$1,895.25                                      | \$1,081.50                                    |
| Industrial Mfg. for Distribution                     | C.1          | \$1,628.00                  | \$4,588.00          | \$2,437.75                                      | \$1,624.00                                    |
| Installed Gauges                                     | C.10.a       | \$555.00                    | \$1,813.00          | \$1,470.00                                      | \$831.25                                      |
| Gas Chromatograph, etc.                              | C.10.b       | \$555.00                    | \$1,813.00          | \$1,400.00                                      | \$761.25                                      |
| Portable Moisture Density Gauges, Pb analyzers, etc. | C.11         | \$555.00                    | \$1,813.00          | \$1,750.00                                      | \$1,111.25                                    |
| Calibration Sources                                  | C.12.a       | \$555.00                    | \$1,813.00          | \$1,750.00                                      | \$1,111.25                                    |
| Calibration Sources (Radium)                         | C.12.b       | \$555.00                    | \$1,813.00          | \$1,349.25                                      | \$710.50                                      |
| Decontamination Services                             | C.13.a       | \$2,368.00                  | \$5,513.00          | \$2,100.00                                      | \$1,461.25                                    |
| Industrial (other) (NORM) (Gauge Service)            | C.13.b       | \$2,368.00                  | \$5,513.00          | \$1,750.00                                      | \$1,111.25                                    |
| Contaminated Equipment                               | C.14         | \$555.00                    | \$1,813.00          | \$1,349.25                                      | \$710.50                                      |
| In-house Industrial Radiography                      | C.2          | \$1,480.00                  | \$9,583.00          | \$3,780.00                                      | \$2,966.25                                    |
| Multiple Job-Site Industrial Radiography             | C.3          | \$1,480.00                  | \$9,583.00          | \$3,780.00                                      | \$2,966.25                                    |
| Gamma Irradiators (Self-Shielded)                    | C.4.a        | \$1,184.00                  | \$3,367.00          | \$1,135.75                                      | \$672.00                                      |
| Gamma Irradiators (>10K Ci)                          | C.4.b.1      | \$2,368.00                  | \$5,735.00          | \$1,750.00                                      | \$936.25                                      |
| Gamma Irradiators (>10K<100KCi)                      | C.4.b.2      | \$22,644.00                 | \$52,133.00         | \$4,462.50                                      | \$3,648.75                                    |
| Gamma Irradiators (>100K<1MCi)                       | C.4.b.3      | \$22,644.00                 | \$52,133.00         | \$8,050.00                                      | \$7,236.25                                    |
| Gamma Irradiators (>1MCi)                            | C.4.b.4      | \$22,644.00                 | \$52,133.00         | \$17,675.00                                     | \$16,861.25                                   |
| Broad Scope Distribution, Specific (Type A)          | C.5.a.1      | \$4,736.00                  | \$16,095.00         | \$5,215.00                                      | \$4,401.25                                    |
| Broad Scope Distribution, Specific (Type B)          | C.5.a.2      | \$4,736.00                  | \$16,095.00         | \$2,765.00                                      | \$1,951.25                                    |
| Broad Scope Distribution, Specific (Type C)          | C.5.a.3      | \$4,736.00                  | \$16,095.00         | \$2,275.00                                      | \$1,461.25                                    |
| GL Distribution (source and/or device evaluation)    | C.5.b        | \$740.00                    | \$1,776.00          | \$1,655.50                                      | \$841.75                                      |

| License Category  | Fee Category | New License Application Fee | Annual Fee, Nominal | Annual Fee, Small Entity [See subparagraph (e)] | Annual Fee, Lower Tier [See subparagraph (f)] |
|---|--------------|-----------------------------|---------------------|---|---|
| GL Distribution (no source and/or device evaluation)      | C.5.c        | \$407.00                    | \$1,184.00          | \$1,184.00                                      | \$967.75                                      |
| Possession Incident to NRC Exempt Distribution            | C.6.c        | \$555.00                    | \$1,813.00          | \$1,739.50                                      | \$925.75                                      |
| Well Logging/Tracers                                      | C.7.a        | \$1,221.00                  | \$3,774.00          | \$2,217.25                                      | \$1,403.50                                    |
| Field Flooding Studies                                    | C.7.b        | \$857.15                    | \$2,933.85          | \$1,750.00                                      | \$1,111.25                                    |
| Nuclear Laundries   | C.8          | \$8,066.00                  | \$17,057.00         | \$2,590.00                                      | \$1,776.25                                    |
| Industrial Research & Development                         | C.9          | \$1,295.00                  | \$3,219.00          | \$1,902.25                                      | \$1,088.50                                    |
| Broad Scope (Academic) (Type A&B)                         | D.1.a        | \$1,998.00                  | \$5,439.00          | \$2,563.75                                      | \$1,750.00                                    |
| Broad Scope (Academic) (Type C)                           | D.1.b        | \$1,998.00                  | \$5,439.00          | \$2,075.50                                      | \$1,261.75                                    |
| Broad Scope (Industrial R&D) (Type A)                     | D.2.a        | \$1,998.00                  | \$5,439.00          | \$2,563.75                                      | \$1,750.00                                    |
| Broad Scope (Industrial R&D) (Type B)                     | D.2.b        | \$1,998.00                  | \$5,439.00          | \$2,292.50                                      | \$1,478.75                                    |
| Broad Scope (Industrial R&D) (Type C)                     | D.2.c        | \$1,998.00                  | \$5,439.00          | \$2,075.50                                      | \$1,261.75                                    |
| Broad Scope (Medical Manufacturer for Distribution) (R&D) | D.3          | \$2,405.00                  | \$5,735.00          | \$2,765.00                                      | \$1,951.25                                    |
| Civil Defense (Emergency Management)                      | E.1          | \$925.00                    | \$3,330.00          | \$1,256.50                                      | \$617.75                                      |
| Civil Defense (Emergency Response)                        | E.2          | \$925.00                    | \$3,330.00          | \$1,188.25                                      | \$549.50                                      |
| Teletherapy Service Co.                                   | F            | \$2,368.00                  | \$5,513.00          | \$1,902.25                                      | \$1,088.50                                    |
| Consultants (Leak Testing Service)                        | G            | \$555.00                    | \$1,813.00          | \$1,349.25                                      | \$411.25                                      |
| GL Devices (except tritium safety signs)                  | GL           | \$0.00                      | \$100.00            | \$100.00  | \$100.00                                      |
| Academic (Non-Broad)                                      | I            | \$1,295.00                  | \$3,219.00          | \$1,400.00                                      | \$761.25                                      |
| Device Evaluation   | J.1          | \$4,595.40                  | \$5,350.20          | \$1,050.00                                      | \$236.25                                      |
| Source Evaluation   | J.2          | \$1,709.40                  | \$2,319.90          | \$875.00  | \$236.25                                      |

| License Category                            | Fee Category | New License Application Fee   | Annual Fee, Nominal | Annual Fee, Small Entity [See subparagraph (e)] | Annual Fee, Lower Tier [See subparagraph (f)] |
|---|--------------|---|---------------------|---|---|
| Radioactive Waste Disposal-Burial           | L.1          | \$154,286.53  | \$155,200.77        | \$39,550.00                                     | \$38,736.25                                   |
| Radioactive Waste Disposal-Incineration     | L.2          | \$154,286.53  | \$155,200.77        | \$39,550.00                                     | \$38,736.25                                   |
| Radioactive Waste, Processing & Repackaging | L.3.a        | \$3,108.00  | \$11,840.00         | \$5,390.00                                      | \$4,576.25                                    |
| Radioactive Waste, Prepack aged             | L.3.b        | \$1,813.00  | \$5,513.00          | \$3,552.50                                      | \$2,738.75                                    |
| Reciprocity                                 | K.           | appropriate nominal annual fee (eligible for Small Entity/Lower Tier) |                     |   |   |

**(e) Small Entity**

The size standards for Georgia small entities are as follows:

1. A small business is a business with annual receipts of \$3.5 million or less except private practice physicians for which the standard is annual receipts of \$1 million or less.
2. A small organization is a not-for-profit organization which is independently owned and operated and has annual receipts of \$3.5 million or less.
3. Small governmental jurisdictions are governments of cities, counties, towns, school districts, or special districts with a population of less than 50,000.
4. A small educational institution is one that is (1) supported by a qualifying small governmental jurisdiction, or (2) one that is not state or publicly supported and has 500 employees or less.

**(f) Small Entity Lower Tier**

Small businesses and not-for-profit organizations with annual receipts of less than \$250,000 and small governmental jurisdictions with populations of less than 20,000 qualify for the lower tier small entity fee.

**(3) Penalties.**

(a) Any person who engages in any of the following conduct shall be guilty of a misdemeanor as found in O.C.G.A. Section [31-13-13](#):

1. Hindering, obstructing, or otherwise interfering with any representative of the Department in the discharge of his official duties in making inspections or impounding radioactive materials as provided in Code Section [31-13-5](#) and [31-13-11](#) respectively; or
2. Violating the provisions of Code Section [31-13-7](#) (permits for disposal of radioactive waste; bonding of permittees), or any Rule or Regulation promulgated there under; or
3. Violating the provisions of Code Section [31-13-12](#) (Prohibited Uses of Sources of Radiation).

(b) Any person who submits any false statements or writings, concealment of facts, and fraudulent documents in matters within the jurisdiction of the Division shall be guilty of a felony as found in O.C.G.A. Section [16-10-20](#):

1. A person who knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact; makes a false, fictitious, or fraudulent statement or representation; or makes or uses any false writing or

document, knowing the same to contain any false, fictitious, or fraudulent statement or entry, in any matter within the jurisdiction of the Division shall, upon conviction thereof, be punished by a fine of not more than \$1,000.00 or by imprisonment for not less than one nor more than five years, or both.

(c) Any person who:

1. Violates any licensing provision of this [31-13-1](#), et.seq., or any Rule, Regulation, or Order issued under [31-13-1](#), et. seq., or any term, condition, or limitation of any license issued under this Chapter; or

2. Commits any violation for which a license may be revoked under rules or regulations issued pursuant to this [31-13-1](#), et. seq., may be subject to a civil penalty, to be imposed by the Division, not to exceed \$10,000.00. If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty.

3. If a violation is found to exist during an inspection or visit and is then found to exist on a subsequent inspection or visit, there shall arise a rebuttable presumption that the violation continued throughout the period of time between the initial inspection or visit and the subsequent inspection or visit.

(d) Whenever the Division proposes to subject a person to the imposition of a civil penalty, it shall notify such person in writing:

1. Setting forth the date, facts, and nature of each act or omission with which the person is charged.

2. Specifically identifying the particular provision or provisions of the Code section, Rule, Order, or license condition involved in the violation; and

3. Advising of each penalty which the Division proposes to impose and its amount.

(e) Such written notice shall be sent by registered or certified mail by the Division to the last known address of such person. The person so notified shall be granted an opportunity to show in writing, within ten days from receipt of such notice, why such penalty should not be imposed. The notice shall also advise such person that upon failure to pay the civil penalty subsequently determined by the Division, if any, the penalty may be collected by civil action.

(f) Upon receipt of a written response from the person so notified, alleging that a penalty should not be imposed, the Director shall consider the response and make a final decision on the appropriateness and amount of the penalty. The Division may, at its discretion, conduct an onsite inspection in order to make a final decision. In making this decision, the Director may, as deemed appropriate by the Director, consider such factors as: errors concerning the amount or nature of the penalty, corrective action taken by the licensee, and approved disposal of radioactive material by the licensee.

(g) The Division shall inform the licensee of its final decision by registered or certified mail to the last known address of the licensee. Within 10 days of receipt of the Division's final determination concerning the civil penalty, the licensee may request an administrative hearing pursuant to the Georgia Administrative Procedure Act, O.C.G.A. [50-13-1](#), et. seq.

**AUTHORITY:** O.C.G.A. [31-13-1](#) et seq., as amended.

**HISTORY:** Rule entitled "Administration" adopted. F. Feb. 24, 1994; eff. Mar. 16, 1994.

**Amended:** F. Oct. 4, 1994; eff. Oct. 24, 1994.

**Amended:** F. Apr. 16, 1997; eff. May 6, 1997.

**Amended:** F. Mar. 29, 2002; eff. Apr. 18, 2002.

**Amended:** F. Aug. 16, 2013; eff. Sept 5, 2013.

**Amended:** F. Jan. 28, 2019; eff. Feb. 17, 2019.

**Amended:** F. Feb. 26, 2020; eff. Mar. 17, 2020.

# Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

## Chapter 391-4. WILDLIFE RESOURCES DIVISION

### Subject 391-4-2. HUNTING REGULATIONS

#### **391-4-2-.72 Provisional Regulations for Newly Added Wildlife Management Areas**

For Ceylon Wildlife Management Area (Camden County) the following species may be hunted in accordance with restrictions set forth herein and the restrictions established in Rules [391-4-2-.60](#) through 391-4-2-.68 except as otherwise specified below:

(a) Deer. All deer hunts are quality buck/antlerless. Legal bucks must have not less than 4 points, one inch or greater, on one side of the antlers or must have an outside spread of not less than 15 inches.

1. Archery: Sept. 12-Oct. 18 and Dec. 6-Dec. 27, 2020. Sign-in.

2. Firearms: Oct 22-24, Nov. 12-14, and Dec. 3-5, 2020. Each firearms deer hunt has a quota of 100 hunters. Check-in.

(b) Small Game: Aug. 15-Oct. 21, Oct. 25-Nov. 11, Nov. 15-Dec. 2, 2020 and Dec. 6, 2020 - last day of February 2021.

(c) Turkey: Apr. 4-10, Apr. 18-24, May 2-8, 2020 and Apr. 3-9, Apr. 17-23, May 1-7, 2021. Each turkey hunt has a quota of 40 hunters and the bag limit is one (1) gobbler per hunter per quota hunt.

(d) Coyote Season: no dogs allowed.

**AUTHORITY:** O.C.G.A. §§ [27-1-4](#), [27-3-15](#).

**HISTORY:** Original Rule entitled "Special Deer Hunts for Physically Disadvantaged Deer Hunters" adopted. F. Sept. 6, 1996; eff. Sept. 26, 1996.

**Repealed:** New Rule entitled "Wildlife Management Areas, Federal Wildlife Areas and Other State Lands Legend" adopted. F. Apr. 30, 1999; eff. May 20, 1999.

**Repealed:** New Rule of same title adopted. F. May 29, 2001; eff. June 18, 2001.

**Repealed:** New Rule of same title adopted. F. May 30, 2003; eff. June 19, 2003.

**Repealed:** F. June 1, 2017; eff. June 21, 2017.

**Adopted:** New Rule entitled "Provisional Regulations for Newly Added Wildlife Management Areas." F. Feb. 10, 2020; eff. Mar. 1, 2020.

# Department 480. RULES OF GEORGIA STATE BOARD OF PHARMACY

## Chapter 480-13. HOSPITAL PHARMACY REGULATIONS

### 480-13-.05 Physical Requirements. Amended

(1) **Area.** A hospital pharmacy shall have within the hospital which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The hospital pharmacy space requirements should be a minimum of 10 square feet per hospital bed, which includes all areas assigned and under the direct control of the Director of Pharmacy.

(a) The pharmacy of substance abuse treatment or mental health facility shall be exempt from the minimum square footage requirement provided that the pharmacy receives a satisfactory inspection from the Georgia Drugs and Narcotics Agency that shows that the pharmacy space is sufficient to supply the needs of the patients and that all aspect of the management and operations of the pharmacy comply with the law and the rules of the Board to ensure that the health, safety, and welfare of the patients served by the pharmacy are protected. No application for licensure of a pharmacy of a substance abuse treatment or mental health facility seeking an exemption shall be approved without a satisfactory inspection.

(b) "Mental health facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with psychiatric disorders.

(c) "Substance abuse treatment facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with substance use disorders.

(2) **Equipment and supplies.** Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. The equipment and physical facilities shall include the following:

(a) Compounding and dispensing area:

1. A refrigerator in operating condition with a thermometer, preferably a biological refrigerator;
2. A sink in operating condition with hot and cold running water;
3. A Class A Balance and an assortment of metric weights if utilizing a Class A Balance or a Class I or II Electronic Balance, if compounding onsite using components which must be weighed;
4. Graduates of assorted sizes;
5. Mortar and pestle;
6. Two (2) spatulas and a counting tray;
7. Typewriter, word processor, or computer with a label printer;
8. Pill tile; and
9. Other equipment as deemed necessary by the Director of Pharmacy.

(b) Parenteral solution additives area as required in [480-13-.06\(2\)\(a\)](#);

1. Laminar flowhood; and

2. Facility for light-dark field examination.

(c) Storage and receiving area;

(d) Manufacturing and packaging area; and

(e) Office space area.

(3) (a) The pharmacy of a substance abuse treatment or mental health facility shall be exempt from (2)(a)(3.), (2)(b)(1.), and (2)(b)(2.) under the following terms and conditions:

1. The Director of Pharmacy attests that the pharmacy will purchase only commercially prepared medications and intravenous preparations;

2. The Director of Pharmacy attests that no compounding will occur on-site;

3. The pharmacy includes the attestations in its application for licensure as a hospital pharmacy; and

4. The pharmacy receives a satisfactory inspection from the Georgia Drugs and Narcotics Agency that shows that in the absence of the equipment, the pharmacy is sufficient to supply the needs of the patients and that all aspect of the management and operations of the hospital pharmacy comply with the law and rules of the Board to ensure that the health, safety, and welfare of the patients served by the pharmacy are protected.

(b) No application for licensure of a pharmacy of a substance abuse treatment or mental health facility seeking an exemption shall be approved without a satisfactory inspection.

(c) "Mental health facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with psychiatric disorders.

(d) "Substance abuse treatment facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with substance use disorders.

(4) Each hospital pharmacy shall maintain a reference library which includes, at a minimum, the following:

(a) Copy of and/or electronic or computer access to the latest edition of the Georgia Pharmacy Practice Act, the Georgia Controlled Substances Act and the Rules and Regulations of the Georgia State Board of Pharmacy;

(b) Copies of and/or electronic or computer access to current reference materials appropriate to the practice of the hospital pharmacy;

(c) Copy of and/or electronic or computer access to the latest edition of the American Society of Health-system Pharmacists Formulary Service;

(d) Compatibility charts;

(e) Current drug interaction references;

(f) Current antidote information;

(g) Copy of and/or electronic access or computer access to the latest edition of text and reference works covering theoretical and practical pharmacy, reference materials on general, organic, pharmaceutical and biological chemistry, toxicology, pharmacology, sterilization and disinfection.

(5) **Storage.** All drugs shall be stored in the hospital pharmacy within designated areas which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage cabinets and unit dose carts at the nursing station shall be locked when the station is not in attendance by nursing personnel.

(6) Controlled drug storage for Schedule II drugs. An enclosed controlled room with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet adequately locked that is permanently affixed to the structure is acceptable.

(7) Unattended areas. Whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(8) **Security.** All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The Director of Pharmacy shall designate in writing, by name and specific area, those persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

(9) **Variances.**

(a) The Director of Pharmacy may submit to the Board a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for granting the variance which relate to the necessary or efficient delivery of health care. After consideration by the Board, the Director of Pharmacy will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for each variance(s) indicated in the letter, and shall be posted next to the Georgia Drugs and Narcotics Agency inspection report.

**AUTHORITY:** O.C.G.A. §§ [26-4-27](#), [26-4-28](#), [26-4-80](#), [26-4-110](#).

**HISTORY:** Original Rule entitled "Physical Requirements" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.

**Repealed:** New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.

**Repealed:** New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

**Amended:** F. Feb. 27, 2017; eff. Mar. 19, 2017.

**Amended:** Feb. 4, 2020; eff. Feb. 24, 2020.